THE ASSOCIATION BETWEEN MENTAL HEALTH AND GOAL ATTAINMENT

Exploring the Association between Mental Health and Goal Attainment for Individuals Enrolled in a Healthy Lifestyles Program

By Arielle Sutton, B.A.

A Thesis Submitted to the School of Graduate Studies in Partial Fulfilment of the Requirements for the Degree Master of Public Health

Lay Abstract

Rates of mental illness are increasing in Canada. Lifestyle changes and setting goals can help improve symptoms of mental illness. This study examined the relationship between mental health and goal achievement for individuals enrolled in a person-centered and holistic program, the healthy lifestyles program. Fifteen participants in the intervention group met weekly for education and peer-support sessions and every month individually with members of the healthcare team in order to develop personalized health goals and an action plan. Fifteen participants in the control arm met every three months to set goals and an action plan with a research assistant. There were reductions in depression, insomnia, and loneliness symptoms between baseline and 9-months in the intervention group. Participants with higher depression, insomnia, and loneliness scores were less likely to meet their goals. Participants in the intervention group were more likely to meet their health goals.

Abstract

Background:
Rates of mental illness have been rising in Canada. Lifestyle changes (e.g., increasing physical activity) can decrease symptoms of mental illness. Setting goals as part of a lifestyle program is integral in changing behavior, though previous literature surrounding the association between goal achievement and mental health is unclear. This study examined the relationship between mental health and goal achievement for individuals enrolled in a person-centered and holistic program, the healthy lifestyles program (HLP), which is rooted in principles of cognitive behavioral therapy and theories of health behavior.

Methods:
A mixed methods pilot pragmatic trial was conducted to test the feasibility and effectiveness of the HLP. Participants in the intervention arm (N=15) met weekly for education and peer-support sessions and every month individually with members of the healthcare team in order to develop personalized healthcare goals and an action plan. Participants in the control arm (N=15) met every three months to set goals and an action plan with a research assistant trained in theories of health behavior. Participants in both arms completed validated health scales every 3 months. Generalized estimating equations were used to model the data.

Results:
There were significant reductions in depression, insomnia, and loneliness scores between baseline and 9-months in the intervention group. Depression (β = -.331, 95% CI [-.458, -.204], *p* < .001), insomnia (β = -.168, 95% CI [-.325, -.010], *p* = .037), and loneliness (β = -.260, 95% CI [-.456, -.064], *p* = .009), significantly predicted mean goal attainment. Partaking in the HLP improves the likelihood that participants meet their health goals (β = 2.359, 95% CI [.943, 3.778], *p* = .001).

Conclusion:
This study aims to discern the relationship between lifestyle interventions, goal achievement and mental health. Partaking in an HLP can reduce risk for mental illness and improve quality of life.

Acknowledgments

There are many people who I would like to thank for supporting me during the process of writing this research project. First, I would like to thank my family for always encouraging me to continue with my education; you are a constant source of support, love, and food.

I would also like to thank my supervisor, Dr. Elizabeth Alvarez and my committee members, Dr. Lawrence Mbuagbaw and Dr. Zena Samaan, for answering all the questions that came up during this laborious process, and making themselves constantly available and willing to help. Your dedication was evident throughout the development of this paper, and it was so appreciated.

Table of Contents

List of Figures and Tables

List of all Abbreviations and Symbols

Cognitive behavioral therapy- CBT
Randomized controlled trial- RCT
Healthy lifestyles program- HLP
The more intensive program- MIP
The less intensive program- LIP
Research Electronic Data Capture- REDcap
The Patient Health Questionnaire-9- PHQ-9
The Generalized Anxiety Disorder-7- GAD-7
The Insomnia Severity Index- ISI
Body Mass Index- BMI
Generalized estimating equations- GEE
Quasi likelihood under independence model criterion- QIC
Akaike Information Criterion- AIC
Variation Inflation Factor- VIF

Declaration of Academic Achievement

This project was supervised by Dr. Elizabeth Alvarez, who provided her guidance throughout the process. Drs. Lawrence Mbuagbaw and Zena Samaan likewise contributed their insights, mainly with the analyses and with their editorial help. Arielle Sutton conducted the literature review, assisted with data collection and data analysis and was the primary author of the current paper.

Background

Rates of chronic disease have been on the rise in Canada.[1] According to a 2014 statistic from the Public Health Agency of Canada, 67% of all deaths per year are caused by four major chronic diseases and conditions: cancer, diabetes, cardiovascular disease and chronic respiratory diseases.[2] Chronic diseases can have a significant impact on individuals as well as their families. While recent medical advancements have allowed Canadians to live longer with chronic diseases, the physical limitations imposed by the disease may result in distress.[3] Those living with chronic diseases often have to adjust their expectations in terms of their employment or lifestyle habits. While many patients grieve their about their condition before adjusting to it, some individuals may develop longer-lasting mental health issues, including depression or anxiety.[3] The link between mental and physical health has been well-established in the literature; those with chronic diseases are more likely to experience mood disorders, as compared to those without chronic diseases.[4–6] One in five Canadians experiences a mental health or addiction problem in their lifetime.[7] This may negatively impact familial relationships.[3] Indeed, past research has demonstrated that sometimes family members are more emotionally affected by illness than the patients themselves.[8,9] It would appear that chronic diseases have adverse and pervasive emotional effects on patients and their families.[10–12]

Chronic diseases also have major detrimental economic effects on families as well as on society at large. While it is difficult to directly compare the economic impact of each disease, as the data is derived from different years, it is valuable to examine each disease individually. According to the Ontario Chronic Disease Prevention Alliance and Ontario Public Health Association, cancer cost $571 per capita in 2002, diabetes cost $306 per capita in 1999, cardiovascular disease cost $640 per capita in 1998, and chronic respiratory disease cost $295

per capita in 1998 on a national level.[13] As well, it was estimated in a 2003 study that mental health problems cost the Canadian health care system a total of $51 billion.[14] Chronic diseases and mental health can cause early death, impact the quality of life of patients, and place an undue economic burden on the health care system.[15]

Risk factors, including tobacco use, alcohol abuse, unhealthy diet and physical inactivity, are responsible, at least in part, for this current rise in chronic disease rates.[2] The rise in mental health rates is also directly affected by poor lifestyle habits, as well as indirectly by the increase in chronic physical illnesses.[2,16] Many of these risk factors are modifiable, suggesting that they are amenable to human intervention.

Lifestyle Interventions

Lifestyle changes, including increasing physical activity, ensuring a proper sleep schedule, and the consumption of healthy foods, can help reduce symptoms of physical and mental illnesses and may be preferred over pharmacological treatments.[17–19] The use of person-centered care, which focuses on providing services that suit the specific needs of each individual, rather than providing one-size-fits-all care, has gained prominence in the field of health care.[20] A patient-centered approach emphasizes a dynamic interaction between the patient and clinician, where a clinician explores the patient's preferences, values and restrictions and helps them make a decision regarding the care that best suits them. They help patients with difficult behavioural changes needed to maintain or improve health.[21] A person-centered approach has been shown to improve disease outcomes and quality of life, and that it is essential to addressing racial, ethnic, and socioeconomic disparities in health care.[21]

Lifestyle programs that incorporate cognitive behavioral therapy (CBT) have been shown to be effective in treating a wide range of individuals with diverse issues, including obese individuals with binge eating disorder,[22] those with depression,[23] and anxiety.[24] CBT is a type of psychotherapy that focuses on challenging dysfunctional or negative cognitions and beliefs. CBT attempts to modify behaviors as well as identify and restructure cognitive distortions, and replace these thoughts with more beneficial ones.[25] CBT can occur either one-on-one with a therapist or in a group setting.[26]

In addition, interventions designed with a theoretical foundation based in theories of health behavior have been shown to be more successful than those without a theoretical base.[27] The theories used most often to develop public health interventions are the social cognitive theory, the transtheoretical model, the health belief model, the theory of planned behavior, and the PRECEDE/PROCEED planning model.[27] Ecological models of health behavior focus on people's transactions with their physical and sociocultural environment, while most other models emphasize individual characteristics and proximal social influences, including family and friends. Healthy behaviors are thought to be most supported when all levels of influence (social circles, environments and policies surrounding an individual) support the behavior change.[28] There are several possible reasons as to why using the theories of health behavior strengthen interventions. It has been proposed that using theories that are well-aligned with the problems and context in the studies explains the success of theory-based interventions. It is also possible that theory-based programs are developed with greater care and structure, although there may be other explanations as well.[27] A systematic review of the use of theories in health behavior research revealed that there is a continuum in which a theory can be used to develop an intervention.[29] At the lowest rung, the intervention is simply informed by the theory, indicating

no or limited application of the theory in specific components of the study. At the next level, the theory is applied, signifying that a framework was specified and several of the constructs from the theory were applied in the intervention. The theory can also be tested in a study, where a theoretical framework is specified, and more than half of the theoretical constructs were measured and tested, or two or more theories were compared with each other. Lastly, a study can be used to create a theory, when constructs from a new or revised theory are specified, measured and analyzed.[29]

Goal Setting

Setting goals as a part of a lifestyle program is integral in changing behavior and improving health. Setting goals leads to increased positive behavioral changes, as compared to not setting goals at all, or setting vague goals.[30] Goals that center around behavioral change (i.e. workout for thirty minutes every day) compared to a physiological change (i.e. lose five pounds every month) are advantageous, as they are within under a person's direct control and result in observable changes.[30] Also, it has been shown that individuals exhibit greater commitment to behavioral changes when the goals are personalized.[30] In one study, 78% of participants who were characterized as overweight or obese participated in a year-long wellness coaching program. Setting personal goals was associated with favorable diet and physical activity lifestyle changes.[31]

In another study, fifty-four people with pre-diabetes participated in an unblinded randomized pragmatic trial entitled the *Avoiding Diabetes Thru Action Plan Targeting* program, which consisted of an electronic medical record-based goal setting tool.[32] The tool ensured that the goals adhered to the widely-used SMART formula (specific, measurable, achievable, realistic

and time-bound), which encouraged patients to focus on concrete goals for lifestyle behavior

change. Those who received the intervention showed an increase total in daily steps compared to

those in the control group (+ 1418 vs – 598 steps, p = 0.007) after six months. There was also a

trend towards weight loss in the intervention compared to the control group (p = 0.11), although

there was no change in glycemic control. Setting goals in conjunction with a lifestyle

intervention program is a practical and cost-effective method of promoting behavioral changes.[32]

While setting goals can help many individuals achieve health goals, and is undoubtedly

better than not setting goals at all, it is sometimes insufficient to instigate behavioral changes.[33]

This is due to the fact that there is often a gap between someone's goal intention and goal

achievement. An intention to achieve a goal does not equip an individual to deal with difficulties

in self- regulation (i.e. initiating and maintaining goal pursuit, dealing with distractions and

competing goals), or with over extending oneself in goal striving.[34] Past research has

demonstrated that having intentions to achieve a goal only moderately predicts actual

achievement of that goal (R^2= 0.28).[35]

Setting an individualized action plan is an effective method that can help individuals put

their goals into action. Action plans are used in conjunction with setting goals, as they outline the

when, where and how the person will achieve their health goals. They also help individuals

identify potential barriers and facilitators of goal achievement.[33] Action plans are often

structured as if-then plans, which contain two parts; 1) situational cues, which are good

opportunities to act, and 2) critical moments and contextualized responses, which are specific

steps required to be effective in attaining goals and desired outcomes.[36] An example of an if-then

plan is "if I encounter situation X, then I will initiate goal-directed behavior Y".[34] A systematic

review of four studies evaluated the effectiveness of if-then plans as a sole intervention or as part

of treatment, in adult patient populations.[36] Results indicated that epilepsy and stroke patients who constructed if-then plans were more likely to adhere to their medication regimen, and chronic back pain patients who developed if-then plans had improved physical capacity (when combined with mental contrasting & cognitive behavioural therapy).[36]

Additionally, results from a meta- analysis with 94 independent studies and more than 8000 participants indicated that an action plan had a positive effect of medium-to-large magnitude on goal achievement.[34] Specifically, an effect size of d=0. 65 was reported, which indicates that participants who developed both goals and an action plan had higher mean goal achievement scores, as compared to those who only set goals.[34] Developing action plans in conjunction with goal setting has been shown to be a very effective method for individuals who wish to achieve their health goals and make a positive behavioral change within their lives.

The Effect of Mental Health on Goal Achievement

Past research suggests that there is a relationship between depression, goal setting, and ultimately, goal achievement. In his paper, Watkins (2011) reviewed the literature surrounding goal pursuit and depression and noted that depression is characterized by a loss of motivation.[37] This results in issues initiating goal pursuit, thereby decreasing the likelihood of meeting goals.[37] This may result in depression, consequently instigating a cycle of failure and depression.[37] Furthermore, another study found that depressed individuals generated less specific goals, as compared to controls.[38] The formation of less specific goals is likely to diminish the motivation associated with goal attainment and result in limited goal progress.[38] It is clear that depression is associated with limited goal progress.

Furthermore, there is limited research concerning goal achievement and other mental health issues. McKinnon and Garvin (2018) examined the association of mental health diagnoses with a 5% weight reduction goal among 402 veterans.[39] Results of the study indicated that the likelihood of goal achievement differed depending on the mental health diagnosis, although at all three time points (6,12, and 24 months), simply having a mental health diagnosis was not associated with greater likelihood of goal achievement.[39] Examining specific diagnoses reveals that post-traumatic stress disorder and drug use disorder were associated with a greater likelihood of achieving a weight loss goal at 12 months, but not at 24 months. Alternatively, anxiety disorder and "other" mental health diagnoses were not associated with a greater probability of meeting health goals at 12 months, but it was a significant association at 24 months.[39] These results indicate that there is no clear association between any mental health condition and goal attainment at 12 or 24 months, thereby warranting follow-up in future studies.

Gollwitzer (2006) conducted a systematic review on the effects of goal setting and if-then plans on goal achievement.[34] In patients with schizophrenia, patients with brain-injury, and patients with heroin addictions, if-then plans had stronger effects on those with psychological issues, compared to other groups. He posits that action plans are especially beneficial for people with psychological issues, because they often have trouble regulating their behavior. Formulating if-then plans is often most helpful for people who have chronic difficulties regulating their behavior, though they are not necessarily more likely to meet their goals, as compared to people who do not have difficulties regulating their behavior.

The Effect of Goal Achievement on Mental Health

In terms of the effects of goal attainment on mental health, Frijda (1986) noted that perceived or expected goal attainment leads to positive emotions and that perceived or expected threats to goal attainment lead to negative emotions.[40,41] One meta- analysis that integrated 85 studies found a significant association between goal striving and subjective well-being (p = .43).[42] However, self-determination theory, a psychological concept on human motivation that was proposed by Edward Deci and Richard Ryan, suggests that not all goals have the same effects on well-being.[43] Specifically, intrinsic goals which include those related to affiliation (the need for intimate and close relationships),[44] generativity (concern for guiding the next generation"),[45] and personal development are associated with greater health and well-being, compared to extrinsic goals, which center around wealth, fame, and attractiveness.[43]

An interesting study in the field was conducted with 96 graduate students in a public health graduate program.[46] Students learned techniques for behavior change (i.e. positive reinforcement and environmental manipulation) and formulated individual behavior modification goals in one of four categories: nutrition, mental health, physical activity, and social support. The primary outcome was the frequency of experiencing anxious or depressed mood during the past month. The intervention lasted for twelve weeks, and there were no reported changes in the frequency of depressed or anxious mood. These results run counter to established research that suggest a worsening of mental health symptoms over time for graduate students.[46] This is significant in suggesting that education surrounding behavior change and goal setting can mitigate a natural worsening of mental health symptoms seen in graduate students. Although the research is limited in the field of goal setting and mental health, it suggests that goal attainment leads to an improvement in mental health outcomes.

Mental Health Services in Ontario

While research suggests that goal setting and action plan formulation is beneficial in terms of improving participants' mental health, this is not common practice in primary-care physician check-ups. It is estimated that 20% of Ontarians will experience a serious mental health issue in their lifetime.[47] Access to mental health services is limited in Ontario; this is due in part to publicly-funded services struggling to keep up with recent high demands.[47] Over the last 10 years, emergency department visits and hospitalizations for children and youth with mental illness and addictions have gone up 63% and 67% respectively.[48] Wait times for mental health and addictions community services can range from eight weeks to over a year.[49] This dire situation is compounded by the fact that privately funded services are often too costly and therefore out of reach for many seeking help. There is not enough being done to fund and expand these services and provide them in community mental health and primary care networks.[50]

The Current Study

There is a need in Ontario for a person-centered program that provides the supports for people to meet self-identified healthcare goals, thereby improving their quality of life and mental health. Given this demand, the current study will examine how a holistic, person-centered program, the healthy lifestyles program, rooted in the principles of CBT and the theories of health behavior, affects the likelihood of participants meeting health goals, as compared to participants who only set health goals. It will also explore how participants' meeting health goals affects their mental health. This research is a part of a larger pilot study that is also examining the feasibility, implementation and scalability of the healthy lifestyles program (see methods section for detailed description of the program).

Research Questions

1) Is there preliminary evidence that suggests that the presence of various mental health issues, namely depression, anxiety, loneliness, or insomnia affect the likelihood of participants meeting health goals over a year-long program?

2) Is there preliminary evidence that suggests a temporal relationship between goal achievement and participant scores on depression, anxiety, loneliness, and insomnia scales, over a year-long program?

3) Is there preliminary evidence that suggests that the healthy lifestyles program facilitates a reduction in mental health symptomology, compared to only setting goals, over a year-long program?

4) Is there preliminary evidence that suggests that the healthy lifestyles program facilitates the achievement of health goals, compared to only setting goals, over a year-long program?

Hypotheses

We hypothesize that those with various mental health issues are less likely to meet their goals, as compared to those without various mental health issues, and that those who achieve their goals are more likely to see improvements in mental health scores over the year-long program. We also hypothesize that participants who partake in the full healthy lifestyles program are more likely to see improvements in their mental health symptoms, and are more likely to meet their health

goals, as compared to those who only set health goals.

Objectives:

Pilot objectives are addressed in the program evaluation portion of this project (not in the current paper).

<u>Primary:</u>

1) To determine the association between various mental health issues (including depression, anxiety, loneliness and insomnia) and the likelihood of meeting health goals.

2) To search for possible effects between meeting health goals and changes in mental health outcomes (including depression, anxiety, loneliness and insomnia).

<u>Secondary:</u>

1) To ascertain whether participation in the healthy lifestyles program affects participants' mental health scores.

2) To investigate whether participation in the healthy lifestyles program affects the likelihood of meeting health goals.

Methods

Ethics Approval

This study was approved by the Hamilton Integrated Research Ethics Board (HiREB; #3793) and was registered on ClinicalTrials.gov (identifier: NCT03258138).

Study Design

This study was a pilot pragmatic randomized controlled trial (RCT) that was designed to evaluate the feasibility and implementation of a novel behavioral intervention program, entitled the healthy lifestyles program (HLP) that was run for one year in Hamilton, Ontario. The current paper is a part of the overall study that will explore only the association between mental health and goal achievement for people participating in the healthy lifestyles program. Pragmatic studies are designed to evaluate the effectiveness of an intervention in a real-life setting. Although this limits the control that the researcher has over the results of the trial, it increases the external validity, thereby allowing the results of the study to be applied to a wide range of people.[51]

The Intervention

Participants in the intervention arm (the more intensive program; MIP) met every month with members of the healthcare team (including a family physician trained in medical cognitive behavioral therapy, a dietician, and an orthopedic surgeon) in order to develop individualized health goals, construct an action plan, and identify any facilitators and barriers to achieving their goals. Participants in the MIP also met weekly for group sessions where they learned a variety of health-related topics, including self-regulation techniques, mindful eating,

proper nutrition practices and theories of health behavior, or discussed progress on their goals

and barriers to reaching their goals. If necessary, participants in the MIP received help in finding

community programs that facilitate a healthy lifestyle.

Alternatively, participants in the control arm (the less intensive program; LIP) set health

goals every three months with the help of a research assistant who was trained in theories of

health behavior. They formulated action plans and identified barriers and facilitators to achieving

their goals. If required, a research assistant also helped the participants find community programs

to help fulfill their needs. Participants in both arms of the study completed validated health scales

at baseline and every three months thereafter to assess changes in goal progress and scores on

health scales.

Recruitment Strategy and Sampling Approach

15 participants were recruited for each arm of the trial. This number accounts for the

ideal number of people participating in small group sessions and for potential attrition

throughout the year.[52]

Recruitment for the present study took place at doctors' offices and community

centers in the Hamilton area. Posters and slides were placed in doctors' offices (with the consent

of the staff) and in community settings, such as community centers, office buildings, and coffee

shops, after obtaining consent from the facility. The study was also advertised in CoffeeNews (a

free local newsletter) and on Twitter. This is a form of non-probability sampling, specifically

volunteer sampling, which is a fast, easy and inexpensive method of recruiting participants.

Setting and Participants

This study was conducted through McMaster University at the David Braley Health Sciences Center in Hamilton, Ontario. In terms of the inclusion criteria, participants in the trial included individuals over the age of 18. Participants were required to speak English at a proficient level in order to understand the informed consent forms, as well as actively engage in the group sessions. Exclusion criteria included unstable mental health conditions, including any violent tendencies. The current study was a pragmatic trial, indicating that there were very few limitations placed on who was permitted to participate in the program.

Randomization and Allocation

Participants were listed in alphabetical order on Microsoft Excel, and using the RAND function, they were assigned a random identifier (ID) number. Participants were individually randomized in a 1:1 ratio. Participants were asked if they knew anyone else participating in the study and if they did, they were randomized to the same condition, in order to prevent contamination. The randomization procedure was completed by a research assistant who was not involved with recruitment.

Data Collection Procedure

Beginning in April 2018, and every three months thereafter for the duration of the year-long program, participants were asked to fill out questionnaires that included demographic information as well as a variety of validated scales used to assess their mental health and health-related quality of life. Baseline medical data were collected using paper-based methods and were

later entered manually by a research assistant into REDcap (Research Electronic Data Capture), a secure online database. All other data collected at baseline and later time points were entered directly by the participant onto REDcap using tablets or laptop computers. A research assistant took physical measures of the participant, including height, weight, waist and hip circumference, and blood pressure. Data on goal setting were obtained from the participant's chart.

All participants were given a unique ID number, which was used when collecting all data. All electronic data were stored in password-protected files, or on REDCap. Only research team members who were involved with data collection had permission to access REDcap, and each member had their own password to access the data. A list of participant IDs and their associated names were kept in a locked cabinet, and only research assistants who were involved with data collection had access to the participant IDs.

Instruments and Measures

Demographic information. The questionnaire included items assessing demographic information, such as: age, gender, marital status, number and age of children, family income level, work status, and lifestyles factors (i.e. smoking and alcohol use). It is important to note that the questionnaire specifically inquired about each participants' gender, that is, whether the participant identified as being male, female or other, and it did not inquire about sex, the biological concept that refers to a participant's reproductive anatomy.

Depression. The Patient Health Questionnaire-9 (PHQ-9) was used to assess depression.[53] It is a 9- item questionnaire, where scores of 5, 10, 15, and 20 represent mild, moderate, moderately severe and severe depression.[53] PHQ-9 scores $\geq$ 10 have a sensitivity of 88% and a specificity of 88% for major depression. In one study, the PHQ-9 was completed by

6000 patients in primary care and obstetrics-gynecology clinics. The internal reliability of the PHQ was very high, with a Cronbach's α of 0.89 in a patient population from a primary care setting and 0.86 in a patient population from an obstetrics-gynecology clinic. Criteria validity was reported to be high; those who scored high (≥ 10) on the PHQ-9 were between 7 to 13.6 times more likely to be diagnosed with depression by a mental health professional.[53]

Anxiety. The Generalized Anxiety Disorder-7 (GAD-7) scale was used to assess anxiety symptoms, where scores of 5, 10, and 15 represent mild, moderate, and severe anxiety.[54] One study that included 2740 adult patients from 15 primary care clinics in The United States from June 2004 to November 2005 found that the internal consistency of the GAD-7 was excellent, with a Cronbach α of 0.92.[54] Test-retest reliability was also good, with an intraclass correlation of 0.83. Further, at a cut point of 10 or greater, sensitivity and specificity exceeded 0.80. Most patients (89%) with GAD had GAD-7 scores of 10 or greater, whereas most patients (82%) without GAD had scores less than 10.[54] The GAD-7 was originally put into REDcap for diagnostic reasons, and therefore participants who did not answer at least "several days" to the question "over the last 4 weeks, how often have you been bothered by feeling nervous, on edge, or worrying a lot about different things", did not have the opportunity to answer the rest of the questions on the GAD-7. This was changed in REDcap for 9- month data collection, and therefore scores on the GAD-7 were only examined at 9 months.

Insomnia. The Insomnia Severity Index (ISI) was used to identify a patient's perception of his or her insomnia symptoms.[55] Each item was rated on a 0–4 scale and the total score ranged from 0 to 28. A higher score suggests more severe insomnia. One study with 145 patients from a sleep disorders clinic used sleep diaries and clinical interviews to validate the ISI.[55] Researchers found that the internal consistency of the ISI was 0.74, which is characterized as moderate.

Another study with 78 patients who participated in an RCT comparing behavioral and pharmacological therapies for insomnia compared the ISI to a clinician's and a significant other's version of the ISI, and polysomnographic data.[55] All patients completed the ISI and a daily sleep diary for a 2-week period at baseline, post-treatment, and at 3-, 12- and 24-month follow-ups. The internal reliability coefficients remained very stable from 0.76 at baseline to 0.78 at follow-up. Also, interestingly, the correlations between the patient's and the clinician's versions of the ISI at the two assessment periods were all significant ($p < 0.01$), and the correlations between the patient's and the significant other's versions of the ISI were also significant at the two assessment periods ($p < 0.01$).[55]

      Loneliness. The DeJong Gierveld Loneliness Scale is a 6-item scale that contains two subscales.[56] One is three items and is used to measure emotional loneliness, that is, missing an intimate relationship with confidants. The other subscale is three items and measures social loneliness, which is defined as missing a wider social network of friends and colleagues.[57] In terms of the reliability of the scale, it was tested in the following countries participating in the United Nations "Generations and Gender Surveys": France, Germany, the Netherlands, Russia, Bulgaria, Georgia, and Japan.[58] Sample sizes varied between 8,158 and 12,828, depending on the country surveyed. With respect to the emotional subscale, the reliability coefficient was 0.81 or higher, for those aged 60-79 years old. In terms of the social loneliness subscale, the reliability coefficients were 0.85 or higher, for those aged 60-79. Results were similar for those aged 18 to 59.[58] In terms of the scale's validity, multivariate regression analyses confirmed the associations with six well-known loneliness-related risk variables (sex, age, partner in household, number of children, subjective health, financial situation), supporting the congruent validity of both the emotional and social loneliness subscales.[59]

Goal attainment. A scale was developed for each individual goal, based on a Likert scale, ranging from 1 (worst case) to 7 (best case). If participants no longer wished to work on a certain goal, they indicated a "0", signifying that the goal had been dropped. When calculating mean goal attainment for each subject, only goals that were created at baseline and that were developed throughout the duration of the program were included in the analyses, and goals that were either dropped or developed at the 3,6, or 9-month follow-ups were not included in the analyses. For each participant, all goal attainment scores were totaled and then divided by the number of goals set by each participant.

Data Analysis

Descriptive statistics were calculated for all participants who were enrolled at baseline, irrespective of whether they later withdrew from the study. Descriptive statistics were also calculated separately for people remaining in the study and people who dropped out, in order to compare characteristics. Findings are reported as counts (percent) or mean (standard deviation) for baseline characteristics.

Clinical and participant-relevant outcomes were calculated for participants in both arms of the study who remained for the duration of the program. Means and standard deviations were calculated for the following outcomes: body mass index (BMI), weight, waist-hip ratio, PHQ-9 score, GAD-7 score, ISI score and De-Jong Gierveld score. All scores on mental health scales were treated as continuous variables and were not dichotomized into severity scores. Information concerning goals, including mean number of goals, mean goal achievement scores, and the categories of the goals (i.e. healthy eating, physical activity, stress management, etc.) were also examined.

Generalized estimating equations (GEE) were used to model the data. GEE is a statistical approach that is based on the quasi-likelihood model and is used for longitudinal data.[60] Due to the fact that the current study used a repeated measures design, ordinary least squares regression could not be used as the observations were not independent of one another.[61] GEE incorporates within-subject and between-subject variations into model fitting, which results in a more robust estimation.[60] The correlation matrix that represents the within-subject variation is estimated as part of the model, and was selected a priori. An autoregressive correlation structure was selected for the present analyses, which indicates that two observations taken close in time within an individual tend to be more closely correlated than two observations taken farther apart for the same individual.[62] A Huber White Sandwich Estimator was used to estimate standard errors, which would allow the estimates to be valid in the case that the correlation structure has been misspecified.[61] Also, importantly, the correctness of the working correlation structure is not important in GEE because the coefficients are still consistent even when the structure has been misspecified.[63,64] A quasi likelihood under independence model criterion (QIC) was used to select the best model, as the Akaike Information Criterion (AIC) cannot be used as it is based on maximum likelihood estimation while GEE is non-likelihood based.[65] The model with the smallest QIC value was chosen as the most parsimonious model.[64] A Variation Inflation Factor (VIF) of greater than 10 was used for ruling out collinearity issues.

In order to answer the first research question regarding the association between various mental health issues and goal attainment, separate GEE models were run for each mental health issue being assessed (including depression, anxiety, insomnia and loneliness). For each GEE performed, the difference between mean goal attainment scores at 9-months and baseline was calculated and entered as the dependent variable. The study arm (intervention or control arm)

and the difference between the 9-month and baseline score on the mental health scale (either the PHQ-9, GAD-7, ISI, or De Jong Gierveld Loneliness Scale) were entered as the independent variables. Each participant's ID number was entered as the subject variable. Multiple models were constructed with demographic variables (i.e. age and sex) entered as covariates and the model with the lowest QIC was selected. Exponentiated beta values are reported, which indicates the odds of the outcome (goal attainment) associated with a one-unit increase in scores on each mental health scale (including depression, insomnia, and loneliness).

With respect to the second research question regarding the direction of the association between mental health and goal attainment (i.e. whether mental health affects goal attainment or vice versa), separate simple linear regressions were conducted. Mental health predictors at an earlier time point were entered as the independent variable, and mean goal attainment from a later timepoint was entered as the dependent variable i.e. baseline PHQ-9 score was entered as the predictor and 3-month mean goal attainment was entered as the dependent variable. This was done for each combination of timepoints using PHQ-9 score, ISI score and De Jong Gierveld score as predictors. Covariates including study arm, age, and gender were included in the model based on the highest adjusted R^2 value.

In terms of the third research question, repeated measures ANOVA were performed in order to ascertain whether there were significant changes over time in clinical and participant-relevant outcomes (as listed above) within an arm of the study,

In regard to the final research question concerning whether participation in the HLP affects the likelihood of participants meeting health goals, a GEE was run. Mean goal attainment (calculated as described above) was entered as the dependent variable, while the treatment group (intervention or control arm) was entered as the independent variable. Each participant's ID

number was entered as the subject variable, and the timepoint (baseline, 3-month, 6-month, 9-month) was entered as the within-subject variable. Exponentiated beta values are reported, which indicates the odds of the outcome (goal attainment) associated with participating in the intervention group, compared to the control group.

No data was missing, and therefore sensitivity analyses for missing data were not performed. Multiple models were constructed with demographic variables (i.e. age and sex) entered as covariates. A quasi likelihood under independence model criterion (QIC) was used to select the best model. A probability value of $p < 0.05$ was used to determine statistical significance. All analyses were performed using SPSS version 25.[66]

Ethics

Before participating in the study, all participants were notified that participation in this study was voluntary, and that they were permitted to withdraw at any time. Participants were required to provide written informed consent. Information regarding the risks and benefits of the study and the procedures involved with the study were communicated to the participants. Due to the nature of the study, participants were not blinded and were aware if they were partaking in the more or less intensive program. Due to the limited number of research assistants, they were also not blinded as they were required for data collection for both arms of the study. Participants were given $30 every time data were collected (every 3 months; for a total of four times) for this study, in an effort to compensate participants for their time.

There was minimal risk associated with participating in the proposed study. There was a small risk associated with initiation or increasing levels of exercise activity. As well, there

was a small risk of psychological distress associated with participants not being able to meet their goals. However, these risks were outweighed by the potential benefits of the study.

Every member of the research team had training on research ethics through the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Course on Research Ethics (TCPS 2: CORE*), and completed the *Tutorial for Researchers Conducting Retrospective Review of Health Records* and the *Primer on Privacy Act.*

Results

Participant characteristics: sociodemographic information

In April 2018, 15 participants enrolled in the control group and 15 participants enrolled in the intervention group. Baseline sociodemographic data for each arm are presented in table 1; data for only 11 participants in the control arm are presented because four participants dropped out of the study before their demographic and medical data were collected. The final sample of the study consisted of 9 participants in the intervention group and 7 in the control group.

Participants in both arms of the study were predominantly female (80% in the intervention group, 81.8% in the control), and participants in the intervention group had a mean age of 57.87 (SD = 11.72), while those in the control group had a mean age of 49.45 (SD = 13.45). It is important to note that many of the baseline characteristics (i.e. age, income brackets, affiliation with a particular religion) are not balanced between the two arms. This is due to the small sample size and the fact that the randomization procedure was performed before any data on baseline characteristics were collected. Also, participants who knew each other were randomized to the same condition (in order to prevent contamination), which may have also contributed to the imbalance of baseline characteristics.

Table 1: Socio-demographic information for participants who enrolled at baseline

		Intervention Arm *n*=15	Control Arm *n*=11 *
		n (%)	**n (%)**
Gender	Female	12 (80.0)	9 (81.8)
	Male	3 (20.0)	2 (18.2)
Marital Status	Common-law	1 (6.7)	2 (18.2)
	Divorced	2 (13.3)	2 (18.2)
	Married	7 (46.7)	3 (27.3)
	Other partner	1 (6.7)	1 (9.1)
	Single	2 (13.3)	1 (9.1)
	Widowed	2 (13.3)	1 (9.1)
Highest Level of Education	Not Graduated from High School	0 (0)	1 (9.1)
	High school	2 (13.3)	0 (0)
	College	8 (53.3)	7 (63.6)
	Bachelor's	4 (26.7)	1 (9.1)
	Master's	1 (6.7)	2 (18.2)
Employment Status	Currently Employed	6 (40.0)	6 (54.5)
	Not Currently Employed	9 (60.0)	5 (45.5)
	On Disability	3 (20.0)	2 (50.0)
	Retired	5 (33.3)	3 (50.0)
	Other	1 (0.07)	0 (0.0)
Income	<$20 000	1 (6.7)	2 (18.2)
	$20 000-50 000	5 (33.3)	3 (27.3)
	50 001-80 000	3 (20.0)	2 (18.2)
	80 001-120 000	2 (13.3)	3 (27.3)
	>$120 000	4 (26.7)	0 (0)
Affiliates with a Particular Religion	Yes	8 (53.3)	1 (9.1)
	No	7 (46.7)	10 (90.9)
		Mean (SD)	
Age		57.87 (11.72)	49.45 (13.45)
*Four participants dropped out before data was collected			

Goal setting

Descriptive information regarding participants' goals, including the mean number of goals set by participants and their mean goal attainment scores are displayed in table 2. Additionally, the types of goals that participants set are presented in figure 1. Most goals related to healthy eating, followed by physical activity, though they also pertained to: general mental health, improving mood, improving sleep, managing finances, managing time, pain, socializing, strengthening relationships, stress management, substance use, weight management, and other.

Table 2: Descriptive information regarding participants' goal setting

Clinical and Participant-Relevant Outcomes	Intervention Group N=9				Control Group N=7			
	Baseline Mean (SD)	3-months Mean (SD)	6-months Mean (SD)	9-months Mean (SD)	Baseline Mean (SD)	3-months Mean (SD)	6-months Mean (SD)	9-months Mean (SD)
Number of goals	2.67 (0.71)	2.89 (0.78)	3.55 (0.88)	3.33 (1.41)	1.71 (0.49)	2.43 (0.79)	2.43 (0.79)	2.57 (0.79)
Goal attainment	1.81 (0.63)	4.68 (1.42)	4.85 (1.28)	5.46 (1.72)	2.07 (1.10)	3.14 (1.03)	4.14 (1.38)	3.71 (1.32)

Figure 1: Goal categories
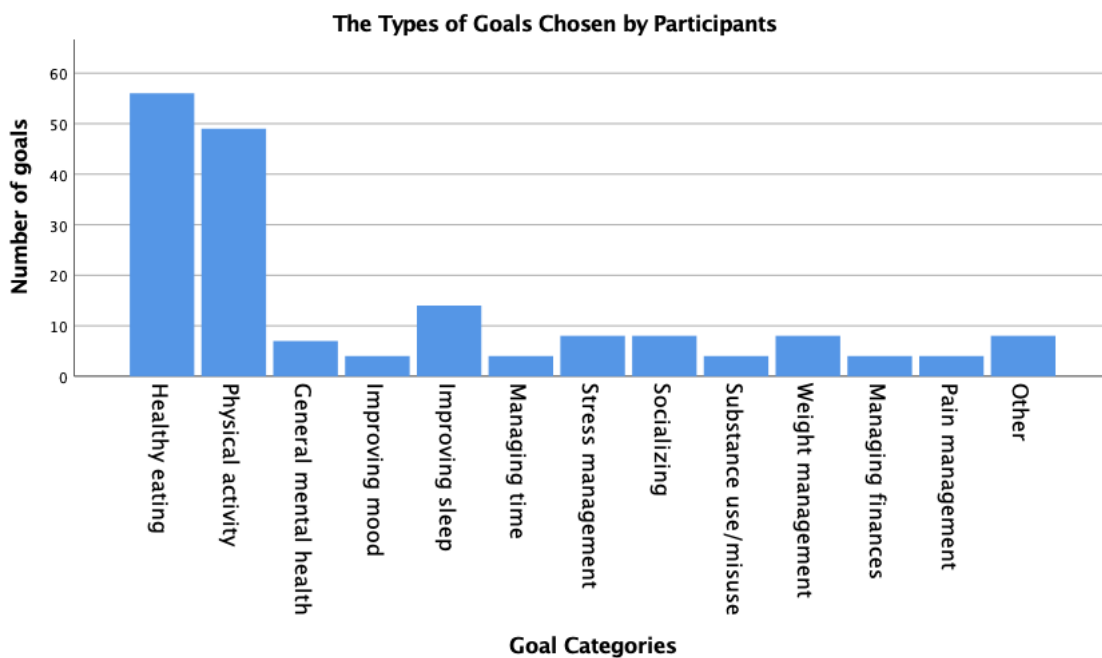
The association between mental health and goal attainment

Separate GEE analyses were used to test whether depression, anxiety, insomnia and loneliness predicted mean goal attainment scores. For all analyses conducted, those with age included in the model had lower QICs, compared to models without age, with both age and gender, and with just gender. Therefore, the most parsimonious model included the participants' study arm, with age and difference in mental health scale between baseline and 9-months as predictors. No VIF exceeded a value of 1.4 in any of the analyses, suggesting that none of the predictors were highly correlated.

First, as displayed in table 3 and appendix 1, depression had a significant negative association with mean goal attainment (β = -.331, 95% CI [-.458, -.204], *p* < .001), after adjusting for study arm and age. The exponentiated beta coefficient is .718, indicating that the odds of participants' attaining their goals is about .718 times higher for every one-point decrease in participants' PHQ-9 score. Insomnia had a significant negative association with mean goal attainment (β = -.168, 95% CI [-.325, -.010], *p* = .037), after adjusting for study arm and age (table 4 and appendix 2). The exponentiated beta coefficient is .846, indicating that the odds of participants' attaining their goals is about .846 times higher for every one-point decrease in participants' ISI score. Loneliness had a significant negative association with mean goal attainment (β = -.260, 95% CI [-.456, -.064], *p* = .009), after adjusting for study arm and age (table 5 and appendix 3). The exponentiated beta coefficient is .771, indicating that the odds of participants' attaining their goals is about .771 times higher for every one-point decrease in participants' De Jong Gierveld score.

It should be noted that it was not possible to perform any analyses using the GAD-7 for anxiety. When the GAD-7 instrument was entered into REDCap, it was entered diagnostically. If

participants did not select "more than half the days" to the first question (which would be

necessary to receive a diagnosis of Generalized Anxiety Disorder), the remaining questions were

not shown to the participant. Therefore, GAD-7 scores are missing for most participants at

baseline, 3-months and 6- months. This was rectified at 9-months.

Table 3: The association between depression scores and mean goal attainment, from generalized estimating equations analysis, adjusted for age and study arm

Parameter	β	Sig.	Exp(B)	95% Confidence Interval For Exp(B)	
				Lower	Upper
Intercept	3.661	.000	5.189	15.994	131.014
Difference in PHQ-9 Score	-.331	< .001	.718	.598	.751
Arm (LIP used as reference)	.570	.367	1.837	.305	3.342
Age	-.038	.001	-.015	.937	.983

Table 4: The association between insomnia scores and mean goal attainment, from generalized estimating equations analysis, adjusted for age and study arm

Parameter	β	Sig.	Exp(B)	95% Confidence Interval for Exp(B)	
				Lower	Upper
Intercept	4.140	.000	62.783	10.291	383.010
Difference in ISI Score	-.168	.037	.846	.722	.990
Arm (LIP used as reference)	-1.405	.100	.245	.046	1.310
Age	-.030	.077	.971	.939	1.003

Table 5: The association between loneliness scores and mean goal attainment, from generalized estimating equations analysis, adjusted for age and study arm

Parameter	β	Sig.	Exp(B)	95% Confidence Interval for Exp(B)	
				Lower	Upper
Intercept	4.966	.000	143.503	38.301	537.666
Difference in De Jong Gierveld Score	-.260	.009	.771	.634	.938
Arm (MIP used as reference)	-1.944	.003	.143	.039	.521
Age	-.028	.069	.972	.943	1.002

The directionality of the mental health and goal attainment relationship

Linear regression analyses were conducted in order to ascertain whether mental health affects goal attainment or vice versa (not shown). The study arm was included in each model as this was determined to be the most parsimonious model based on the adjusted R^2 value. No depression scores significantly predicted mean goal attainment at a later time point. Specifically, baseline depression scores did not predict 3- month (β = .077, 95% CI [-.066, .220], p = .264), 6-month (β = .016, 95% CI [-.141, .173], p = .831) or 9 month goal attainment (β = .138, 95% CI [-.028, .304], p = .095), 3-month depression scores did not predict 6-month (β = -.064, 95% CI [-.265, .137], p = .504) or 9 month goal attainment (β = .083, 95% CI [-.153, .320], p = .460), and 6-month depression scores did not predict 9-month goal attainment (β = .078, 95% CI [-.252, .408], p = .616).

Baseline insomnia scores did not predict 3- month (β = .016, 95% CI [-.144, .175], p = .836) , 6-month (β = -.107, 95% CI [-.261, .047], p = .157) or 9 month goal attainment (β = .073, 95% CI [-.119, .265], p = .425), 3-month insomnia scores **DID** predict 6-month goal attainment scores (β = -.166, 95% CI [-.282, -.050], p = .009), though it did not predict 9 month goal attainment (β = -.026, 95% CI [-.205, .154], p =.761) and 6-month insomnia scores did not predict 9-month goal attainment (β = .051, 95% CI [-.174, .275], p = .634).

No loneliness scores significantly predicted mean goal attainment at a later time point. Specifically, baseline loneliness scores did not predict 3- month (β = -.103, 95% CI [-.322, .116], p = .327) , 6-month (β = -.019, 95% CI [-.256, .219], p = .868) or 9 month goal attainment (β = .101, 95% CI [-.173, .375], p = .440), 3-months loneliness scores did not predict 6-month (β = .019, 95% CI [-.369, .408], p = .915) or 9 month goal attainment (β = .207, 95% CI [-.234, .648],

$p = .330$), and 6-month loneliness scores did not predict 9-month goal attainment ($\beta = .075$, 95%

CI [-.393, .543], $p = .733$).

The association between participation in the healthy lifestyles program and changes in mental health scores

Clinical and participant-relevant outcomes at each timepoint (baseline, 3-months, 6-months and 9-months) are presented in table 6. Line graphs displaying the overall trends of outcomes in each arm are presented in appendices 4-9. Repeated measures ANOVA were performed to determine if there were significant differences in clinical and participant-relevant outcomes in each arm over time (table 7). A Greenhouse-Geisser correction was used when the assumption of sphericity was not met. Importantly, there was a significant decrease in depression, insomnia and loneliness scores, and a significant improvement in general health scores in the intervention group only.

Table 6: Clinical and participant-relevant outcomes of participants in each arm

Clinical and Participant-Relevant Outcomes	Intervention Group N=9				Control Group N=7			
	Baseline Mean (SD)	3-months Mean (SD)	6-months Mean (SD)	9-months Mean (SD)	Baseline Mean (SD)	3-months Mean (SD)	6-months Mean (SD)	9-months Mean (SD)
Body Mass Index (BMI)	42.33 (8.52)	42.05 (8.00)	42.51 (8.15)	41.96 (8.07)	30.04 (5.25)	29.41 (5.67)	29.37 (4.86)	29.99 (4.67)
Weight (kg)	110.23 (27.09)	109.38 (25.17)	110.62 (25.87)	109.28 (25.94)	88.3 (7.59)	86.36 (9.07)	86.54 (8.78)	88.44 (9.09)
PHQ-9	7.56 (5.27)	3.67 (3.24)	4.44 (2.60)	2.78 (2.33)	6.71 (4.72)	6.28 (4.57)	5.00 (3.06)	6.57 (4.43)
SF-36 (general health)	35.00 (14.58)	46.67 (22.91)	52.22 (22.10)	61.11 (25.71)	57.86 (25.64)	61.43 (19.09)	64.29 (17.66)	62.86 (19.76)
ISI	9.56 (5.00)	6.78 (5.54)	5.67 (4.90)	2.33 (2.55)	9.71 (4.39)	8.00 (4.69)	6.00 (2.77)	6.57 (3.31)
De-Jong Gierveld	3.22 (2.82)	0.89 (0.93)	1.33 (1.73)	2.11 (2.26)	3.00 (3.92)	2.71 (2.93)	2.29 (2.29)	2.43 (2.94)
PSS 10	14.89 (5.82)	11.11 (4.99)	11.22 (3.70)	9.33 (4.06)	14.57 (5.68)	14.57 (5.86)	12.00 (4.58)	11.29 (7.87)

Table 7: Results of repeated measures ANOVA to assess changes in clinical and participant-relevant outcomes of participants between baseline and 9-months within each arm

Clinical and participant-relevant outcomes	Intervention Arm			Control Arm		
	F statistic	P value	Difference Mean (SD)	F statistic	P value	Difference Mean (SD)
BMI	$F_{(3,24)}=0.780$	0.517	-0.36 (1.31)	$F_{(3,18)}=0.928$	0.447	-0.04 (1.87)
Weight	$F_{(3,24)}=0.781$	0.516	-0.95 (3.34)	$F_{(3,18)}=0.904$	0.392	0.14 (6.05)
PHQ-9	$F_{(3,24)}=3.708$	0.025*	-4.78 (4.52)	$F_{(3,18)}=0.524$	0.671	-0.14 (2.85)
SF-36 (general health)	$F_{(3,24)}=9.399$	<0.001*	26.11 (19.33)	$F_{(3,18)}=0.836$	0.491	5.00 (11.55)
ISI	$F_{(3,24)}=5.690$	0.004*	-7.22 (4.74)	$F_{(3,18)}=3.070$	0.054	-3.14 (2.79)
De Jong Gierveld	$F_{(3,24)}=4.491$	0.012*	-1.11 (2.26)	$F_{(3,18)}=0.466$	0.710	-0.57 (1.99)
PSS-10	$F_{(3,24)}=2.406$	0.092	-5.55 (4.90)	$F_{(3,18)}=1.038$	0.400	-3.29 (5.99)

* Represents statistical significance at the p<0.05 level

Clinical and participant-relevant outcomes for participants who dropped out of each arm of the study are presented in table 8. Participants who dropped out of the control group had higher depression scores ($M = 12.25$, $SD = 6.29$) compared to those who dropped out of the intervention group ($M = 3.25$, $SD = 3.86$). Those in the control group also had higher insomnia scores ($M = 13.50$, $SD = 1.73$), compared to the intervention group ($M = 3.75$, $SD = 2.50$), and had higher perceived stress scores ($M = 22.50$, $SD = 3.87$), compared to the intervention group ($M = 14.00$, $SD = 6.10$). Last, there were more people who dropped out of the control arm with diagnosed generalized anxiety disorder ($n = 3$), compared to those who dropped out of the intervention group ($n = 0$). A comparison of participant-relevant and clinical outcomes at baseline between those who remained and those who dropped out of each arm is presented in table 8. Participants who dropped out of the control group had higher depression scores ($M = 12.25$, $SD = 6.29$), compared to those who remained in the control group ($M = 6.71$, $SD = 4.72$). Those who dropped out of the control group also had higher insomnia scores ($M = 13.50$, $SD = 9.71$), compared to those who remained in the control group ($M=9.71$, $SD = 4.39$), higher loneliness scores ($M = 5.50$, $SD = 4.80$), compared to those who remained ($M = 3.00$, $SD = 3.92$), higher perceived stress scores ($M = 22.50$, $SD = 3.87$), compared to those who remained ($M = 14.57$, $SD = 5.68$), and more people diagnosed with generalized anxiety disorder ($n = 3$), compared to those who remained in the study ($n = 0$). In terms of the intervention group, those who dropped out had lower depression scores ($M = 3.25$, $SD = 3.86$), compared to those who remained in the study ($M = 7.56$, $SD = 5.27$), as well as lower ISI scores ($M = 3.75$, $SD = 2.50$), compared to those who remained ($M = 9.56$, $SD = 5.00$), lower loneliness scores ($M = 2.50$, $SD = 2.38$), compared to those who remained ($M = 3.22$, $SD = 2.82$), and the same number of

participants with generalized anxiety disorder ($n = 0$), compared to those who remained in the

study ($n = 0$).

Table 8: Clinical and participant-relevant outcomes of those who dropped out and remained in the study

Clinical and Participant-Relevant Outcomes	Intervention				Control			
	Dropped out of the program *		Remained in the program		Dropped out of the program **		Remained in the program	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Body Mass Index (BMI)	4	25.54 (3.69)	9	42.33 (8.52)	4	36.85 (5.26)	7	30.04 (5.25)
Weight (kg)	4	79.63 (10.59)	9	110.23 (27.09)	4	102.91 (15.93)	7	88.3 (7.59)
PHQ-9	4	3.25 (3.86)	9	7.56 (5.27)	4	12.25 (6.29)	7	6.71 (4.72)
SF-36 (general health)	5	59.00 (12.94)	9	35.00 (14.58)	4	33.75 (7.50)	7	57.86 (25.64)
ISI	4	3.75 (2.50)	9	9.56 (5.00)	4	13.50 (1.73)	7	9.71 (4.39)
De-Jong Gierveld	3	2.50 (2.38)	9	3.22 (2.82)	4	5.50 (4.80)	7	3.00 (3.92)
PSS 10	3	14.00 (6.10)	9	14.89 (5.82)	4	22.50 (3.87)	7	14.57 (5.68)
GAD-7 (number with GAD)	4	0	9	0	4	3	7	0

*Data was collected to the full extent possible. Some participants dropped out mid-way through the baseline data collection phase, so partial data is presented the table above.
**Four participants dropped out before data collection began and baseline data was collected for four participants.

The association between participation in the healthy lifestyles program and goal attainment

A GEE analysis was used to test if participation in the healthy lifestyles program affects the likelihood of meeting health goals. Results indicated that compared to the control arm, participants in the intervention arm were more likely to meet health goals ($\beta = 2.359$, 95% CI [.943, 3.778], $p = .001$), after controlling for age and gender (table 9). The exponentiated beta coefficient is 10.58, indicating that the odds of participants' attaining their goals is about 10.58 times higher for participants in the intervention group, compared to those in the control.

Table 9: The association between study arm and mean goal attainment, from generalized estimating equations analysis, adjusted for age and gender

Parameter	β	Sig.	Exp(B)	95% Confidence Interval for Exp(B)	
				Lower	Upper
Intercept	4.915	.002	136.330	6.671	671.987
Arm (LIP used as reference)	2.359	.001	10.584	2.569	43.605
Gender	-1.340	.160	.262	.040	1.699
Age	-.043	.039	.958	.920	.998

Discussion

Main findings

Results indicate that there are significant negative associations between depression, insomnia, loneliness and goal attainment. Both depression and goal attainment and loneliness and goal attainment change simultaneously over time, suggesting that one construct does not instigate change in the other, and they move in tandem. Three-month insomnia scores significantly predicted six-month goal attainment scores, perhaps suggesting that insomnia symptoms may influence goal attainment, though other earlier timepoints of insomnia symptoms did not significantly predict later goal attainment scores; therefore, more research is required to further elucidate this relationship. Also, the healthy lifestyles program was effective in reducing symptoms of depression, insomnia, and loneliness, and in improving general health. In addition, those who dropped out of the control group had substantially poorer mental health symptoms compared to those who dropped out of the intervention group, suggesting that this program is better geared toward high-risk participants who require a more intensive program. Lastly, it was found that those who participated in the full healthy lifestyles program were more likely to meet goals, compared to those who did not participate.

Strengths and limitations

The generalizability of the results is limited as approximately 80% of the sample in both arms consisted primarily of females. Also, while anyone over the age of 18 was permitted to enroll in the study, the mean age in the intervention arm was approximately 58 years old each arm and it was 49 years old in the control group. This further restricts the generalizability of these results as the effects of the HLP is largely unknown in the young adult population.

However, due to the fact that this study was pragmatic, and there were few criteria for exclusion, a wider range of participants were included in the study, which ultimately increases the external validity of the results.

Also, due to the fact that the current study was a pragmatic trial, there were very few inclusion criteria, so participants with clinical diagnoses were not recruited specifically. Therefore, there were not enough participants with clinical diagnoses of depression in the current study to be able to conclude that non-depressed participants were more likely to reach goals, as compared to depressed participants.

Also, participants were required to self-report their mental health symptoms through the use of validated health scales, without the use of clinical ratings. Self-report and clinician ratings each provide unique information that is relevant to clinical prognosis, and therefore some pertinent information may have been lost due to the methods used in the current study.[67] However, the use of clinician-rated scales is costly and puts additional requirements on clinicians' training and consultation times.[67] Past research has shown that there is a moderate to strong correlation between clinician-rated scales and self-report questionnaires, and cheaper self-report instruments are quick, reliable and valid.[68]

Furthermore, the staff and participants were not blinded to the intervention, as this was not possible due to the vast differences between the two arms of the study. Research suggests that nonblinded patients may differ from blinded patients in how they report symptoms or in the quality of the doctor-patient relationship, inducing dissimilar rates of co-intervention, attrition and placebo effect.[69] However, the risk of co-intervention is not a concern for the present study as it is pragmatic, and interventions outside of the trial are not problematic.

Due to the long duration of the study, there were high dropout rates. This may have introduced attrition bias into the study, indicating that those who dropped out of the study were different from those who continued.[70] These differences were evaluated to the full extent possible and were found to be useful for future recruitment considerations. However, the long duration of the study proved to be necessary when attempting to discern the temporality of the relationship that exists between mental health and goal attainment.

Lastly, it is important to note that this study is a pilot study and the main purpose was to determine the feasibility and implementation considerations (other study). This information will be used to inform a larger randomized trial in the future. Nonetheless, the results of the present study achieved statistical significance. This was especially notable given the small sample size and further supports the strength of the association being studied.

How the current study fits in with the broader literature

Research investigating the association between mental health issues and goal attainment has been sparse, particularly in those participating in a behavioral lifestyle intervention. The current study examined those participating in the healthy lifestyles program- an intervention that is holistic, person-centered, and rooted in the principles of CBT and theories of health behavior. This study sought to add to the limited literature that currently exists on how mental illness affects the probability of meeting health goals.

Goal setting

When examining the descriptive data surrounding goal setting, it was interesting to note that weight management was not often chosen as a goal. This was due to the fact that the

research assistant working with control arm participants and the healthcare team working with intervention arm on goal setting were cautious regarding setting goals that specifically involved weight loss. Past research has found that focusing on the process (i.e. dietary behaviors) rather than on the outcome of dieting (weight loss) is associated with more successful goal pursuit and achievement.[71] Therefore, many more goals focused on improving physical activity and eating habits, rather than on the weight loss outcome.

The association between mental health and goal attainment

As hypothesized, this study found a significant negative association between mental health and goal attainment. This was in keeping with past research that found that depressive symptomatology is associated with issues initiating goal pursuit, which decreases the likelihood that participants meet their goals.[37]

As expected, GEE analyses revealed that insomnia was also associated with a reduced likelihood of meeting goals. To the best of our knowledge, no studies have examined this association. This finding is not surprising considering the known relationship between depression and goal attainment, and the relationship that exists between depression and insomnia; there is considerable symptom and diagnostic criteria overlap between depression and insomnia.[72]

Analyses also revealed that participants who reported increased levels of loneliness were less likely meet their goals. Again, to the best of our knowledge, no study thus far has examined this association. This is especially interesting because loneliness, unlike depression and insomnia, is not a clinical diagnosis. However, loneliness is an exceedingly important construct to study because of its connection to both physical and mental disorders, including: depression, alcohol abuse, child abuse, sleep problems, personality disorders, Alzheimer's disease, diabetes,

autoimmune disorders, cardiovascular diseases, obesity, physiological aging, cancer, and poor hearing.[73] The finding that loneliness predicts reduced goal attainment scores reinforces the idea that it is difficult for isolated individuals to make behavioral changes in their lives. Human beings are a social species who require meaningful relationships. People often see their own value reflected in those around them and past research suggests that there is a positive association between the specific bonds within families and chronic disease management outcomes.[74] This idea is the essence of ecological models of behavior change that emphasize community and environmental influences on health behaviors.[28]

Lastly, this study attempted to discern the directionality of the relationship that exists between mental health and goal attainment; that is, whether a decrease in depressive symptoms results in an increase in goal attainment scores, or whether an increase in goal attainment scores causes a decrease in depressive symptomology. Past research has yet to examine the temporality of this relationship. Depression scores from earlier timepoints did not predict later mean goal attainment scores. This suggests that depression scores and goal attainment scores move together, in unison, rather than one causing changes in the other. Interestingly, 3-month insomnia scores significantly predicted 6-month goal attainment scores, though no other timepoints were significant. While it is possible that this indicates that a reduction in insomnia symptoms cause an increase in goal attainment, it is difficult to conclude this based on one timepoint, and further follow-up is required. Finally, loneliness scores from earlier timepoints did not predict later mean goal attainment scores, also suggesting that the two constructs change simultaneously over time.

<u>What role did the healthy lifestyles play in participants' mental health?</u>

This study assessed multiple mental health outcomes for participants. As expected, those in the intervention group experienced significant reductions in depression, insomnia, loneliness and perceived stress. The combination of education sessions, peer support sessions, meetings with the healthcare team, goal setting and action plan formulation aided participants in addressing their mental health concerns. Providing participants with the tools, skills and supports assisted them with reducing their mental health symptoms. There were no significant reductions in these participant-relevant outcomes in the control group, signifying that merely goal setting without the other supports involved, was not sufficient to reduce mental health symptomatology. It is also interesting to examine those who dropped out of the study. The mean PHQ-9 score in the participants who dropped out of the control group was approximately four times higher than those who dropped out of the intervention group, the mean ISI score was approximately three times higher, the mean general health subscale of the SF-36 was approximately twice as low in the control group (with higher scores denoting better health), and three people in the control group were diagnosed with generalized anxiety disorder, compared to none who dropped out of the intervention arm. Also, those who dropped out of the control arm had worse mental health symptoms compared to those who remained in the control arm and those who dropped out of the intervention arm had better mental health symptoms, compared to those who remained in the intervention arm for the duration of the study. While there were too few participants who dropped out to be able to conduct formal analyses, it is interesting to examine these trends. It is hypothesized that those who dropped out of the control arm of the study had worse mental health symptomatology, and likely felt they needed a more intense intervention to help combat their mental health issues. In contrast, those who dropped out of the intervention group had relatively

mild mental health symptomatology. It is possible that the year-long weekly meetings were too intense for people who did not require such an involved intervention.

The association between program participation and goal attainment

GEE analyses affirmed that participants in the intervention arm, who were given the opportunity to participate in the full program, were more likely to meet their goals, as compared to control arm participants. This was expected even though the control group was given a minor intervention that consisted of goal setting and action plan formulation with the help of a research assistant trained in theories of health behavior. While it is true that goal setting leads to increased positive behavioral changes,[30] and action plans are an effective method of helping individuals put their goals into action,[34] the HLP is a holistic intervention based on CBT and behavioral theories that provide extra support for participants. Lifestyle programs that incorporate CBT have been shown to be effective in facilitating modification of dietary habits, weight, cardiovascular disease and diabetes risk factors,[75] and interventions designed based in theories of health behavior have been shown to be more successful than those without a theoretical base.[27] The HLP consists not only of the determination of participant goals and action plans and the identification of barriers and facilitators, but also healthy lifestyle education, peer support sessions, and meetings with a healthcare team. Therefore, it was expected that participants in the intervention group who received more supports would have a greater likelihood of meeting their health goals.

Implications for policy and practice

These findings, along with a full program evaluation (separate study looking at feasibility and implementation factors), will help inform a scaled up program that will be expanded to run with a greater number of people. This could include running the program at a fitness facility,

holding family and community events, and including physiotherapy sessions. Control-arm participants will be given an opportunity to participate if the full program is run again.

This study revealed an important association that exists for participants who were enrolled in a year-long program, but it does not address the maintenance component involved with goal setting and long-term behavioral change. The researchers are extending the study and following up with participants every six months for two years. It will be important to continually assess whether participants continue to use strategies they learned in the program to work on their mental health issues and their goals. In addition, the current project was funded by in-kind contributions from McMaster Faculty. Moving forward, funding must be considered for providing this or similar programs.

Implications for research

The findings of this study provide directions for future research. As the sample was predominantly female, future research should focus on replicating this research in males. Past research has shown that there are vast gender differences in mental health disorders and gender analyses in epidemiological data can be helpful to understand these relationships.[76] Future research could examine gender differences in the association between mental health and goal attainment.

Future research could also stratify individuals based on their clinical diagnosis of a mental disorder. This could help discern whether the actual presence of mental illness is associated with reduced likelihood of attaining goals, or whether the mere presence of symptomatology is sufficient to account for this association. The present study did not possess enough participants with clinical specific diagnoses to be able to explore this question. Also, it

would be interesting for future research to examine other mental health issues, including anxiety, and consider their relationship with goal achievement. As well, previous literature suggests that there are mixed results regarding other mental health diagnoses' association with goal attainment. One study found that post-traumatic stress disorder and drug use disorder were associated with a greater likelihood of achieving a weight loss goal at 12 months, but not at 24 months. Alternatively, anxiety disorder and "other" mental health diagnoses were not associated with a greater probability of meeting health goals at 12 months, but it was a significant association at 24 months.[39] It would be beneficial for future research to examine these associations in greater detail and replicate these results.

Also, it would be important to conduct subgroup analyses to determine whether the intervention was more effective for those with psychological issues, as compared to those without mental health issues. It was not possible to corroborate the systematic review conducted by Gollwitzer which found that action plans were especially beneficial for people with psychological issues, because they often have trouble regulating their behavior.[34] There were not enough cases of specific mental health diagnoses to be able to power the analyses sufficiently in the current sample, but it could be examined in a future trial. This information will be particularly useful in understanding the type of person that the intervention works best for, in order to tailor the recruitment process and work with individuals who will benefit most from the program.
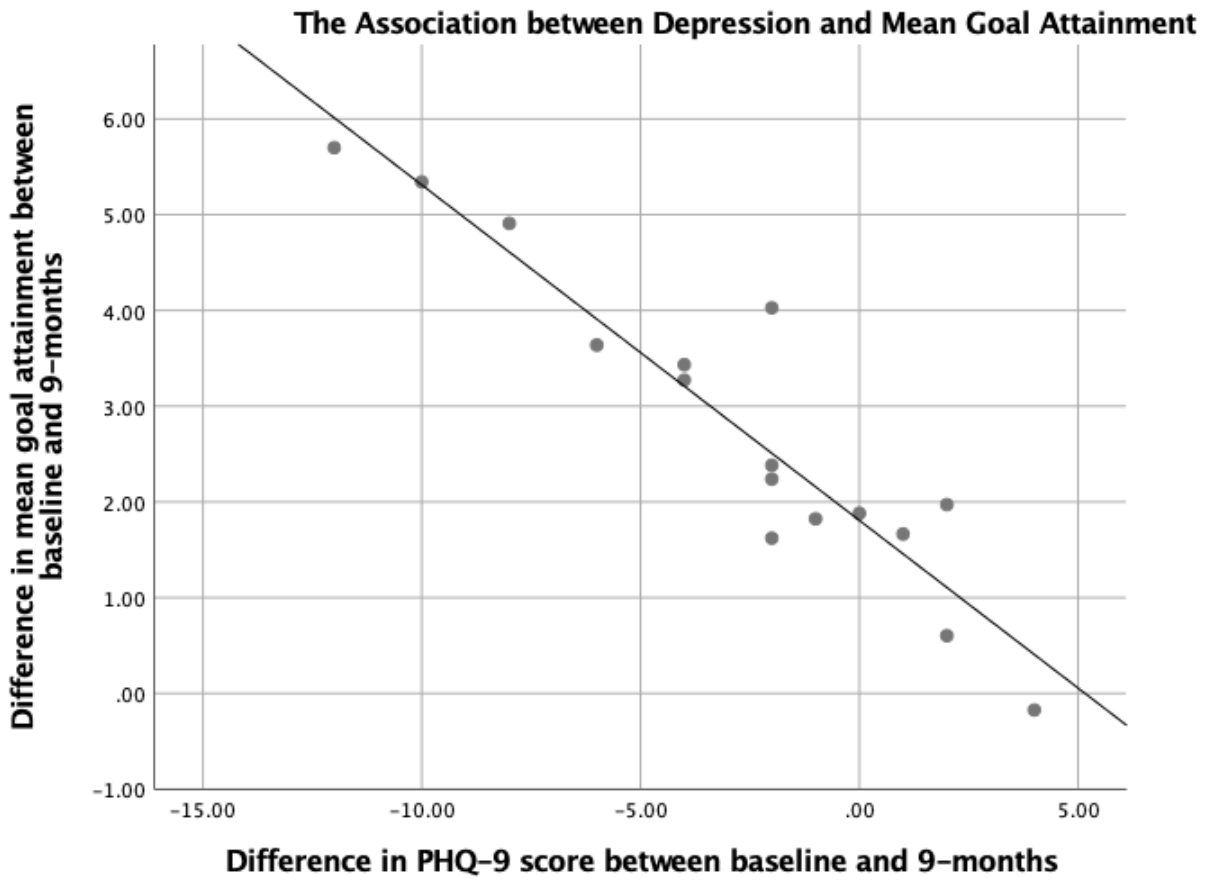
Moreover, the results exhibited a significant reduction in clinical and participant-relevant outcomes, including depression, insomnia, and loneliness symptoms, and an improvement in overall general health, over the course of the 9-months. Looking forward, it will be interesting to determine whether clinical outcomes (including weight, BMI, waist-hip ratio, blood pressure)

also improve over longer amounts of time. It is likely that a year-long program was an insufficient amount of time to change clinical indicators, though these should be examined in the long-term.

Conclusion

This study highlighted the fact that mental health issues can be a significant barrier to individuals achieving their goals and making significant health behavior changes. Participating in a lifestyle program that includes education sessions, peer support sessions, visits with a healthcare team, goal setting, and the formulation of an action plan, can help participants manage their mental illness issues and improve their overall quality of life, thereby facilitating the achievement of their health goals.

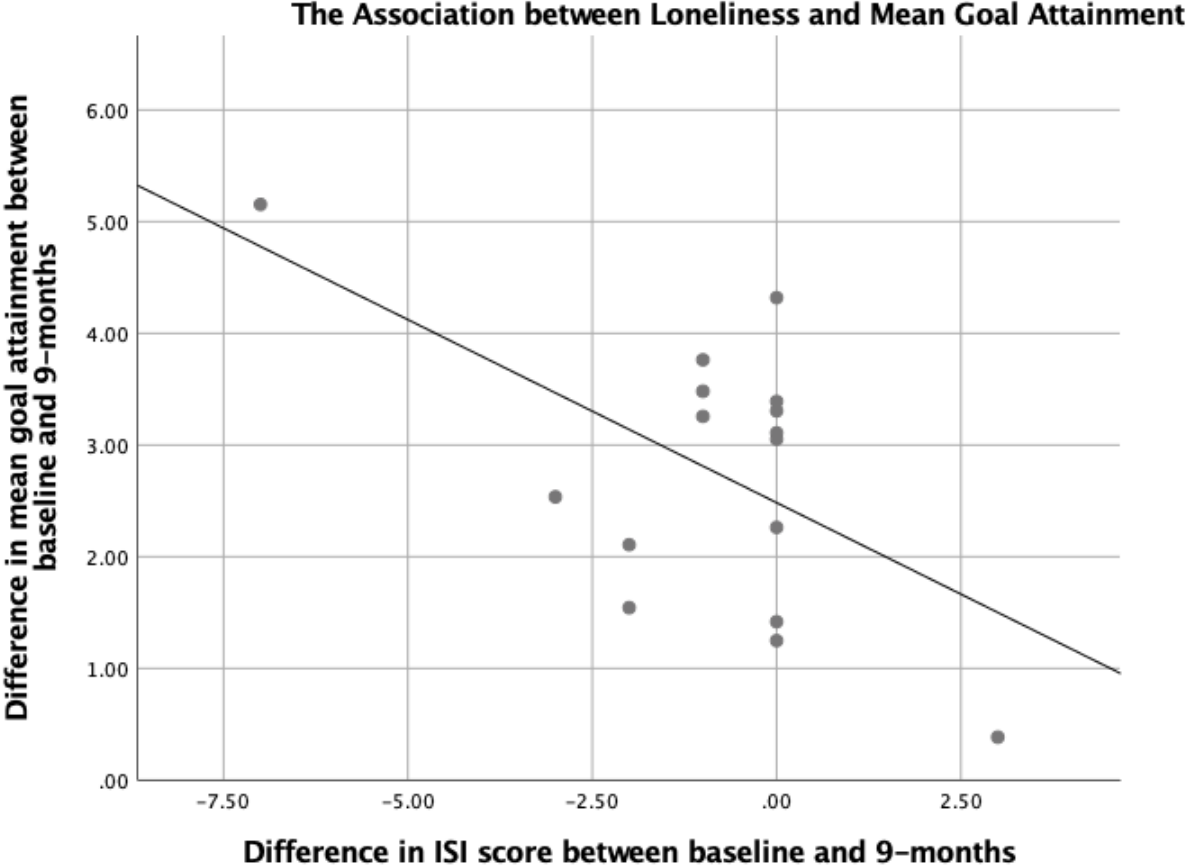Appendix 1. The association between depression and mean goal attainment

The Association between Depression and Mean Goal Attainment

Difference in mean goal attainment between baseline and 9-months (y-axis)

Difference in PHQ-9 score between baseline and 9-months (x-axis)

Appendix 2. The association between insomnia and mean goal attainment


The Association between Insomnia and Mean Goal Attainment
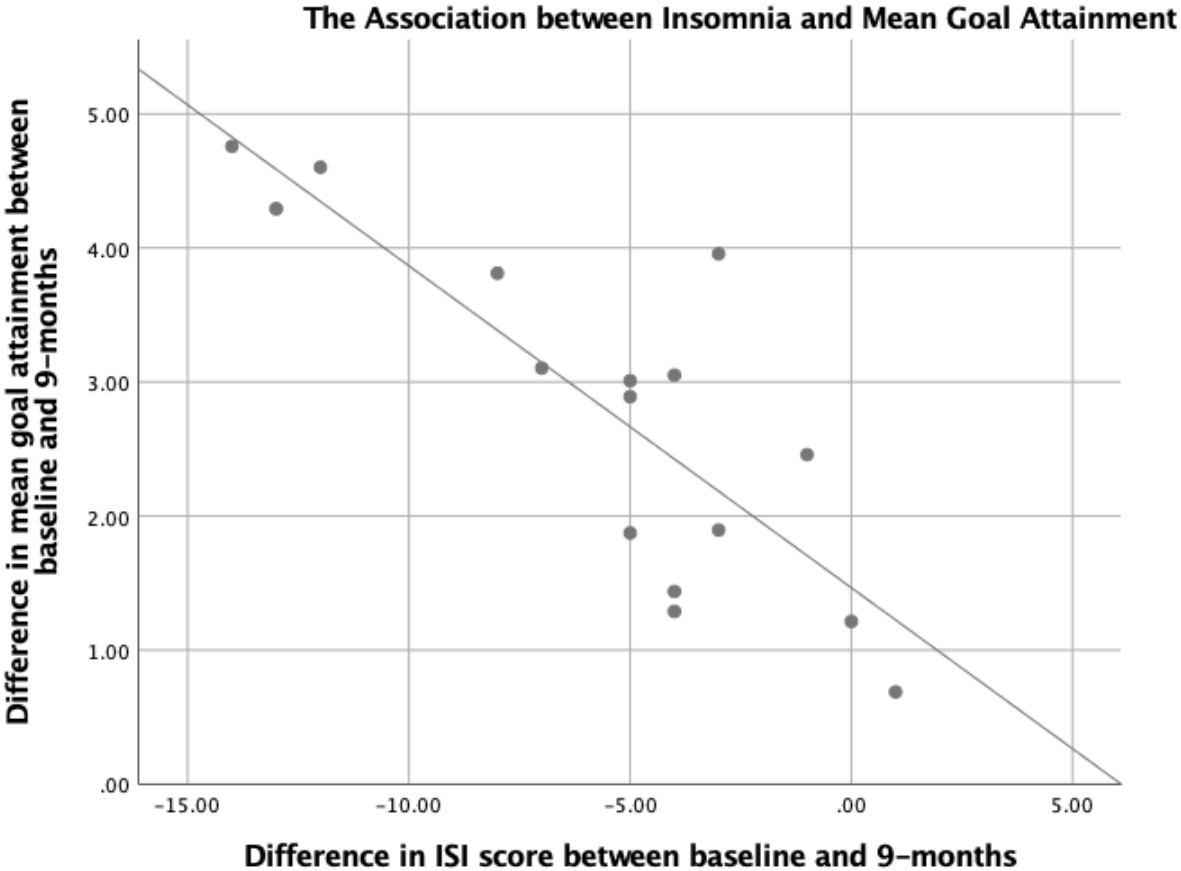
Appendix 3. The association between loneliness and mean goal attainment

The Association between Loneliness and Mean Goal Attainment

Difference in mean goal attainment between baseline and 9-months (y-axis)

Difference in ISI score between baseline and 9-months (x-axis)

Appendix 4. A line graph displaying the overall trend in BMI over time in each arm

The change in mean BMI over time in each arm
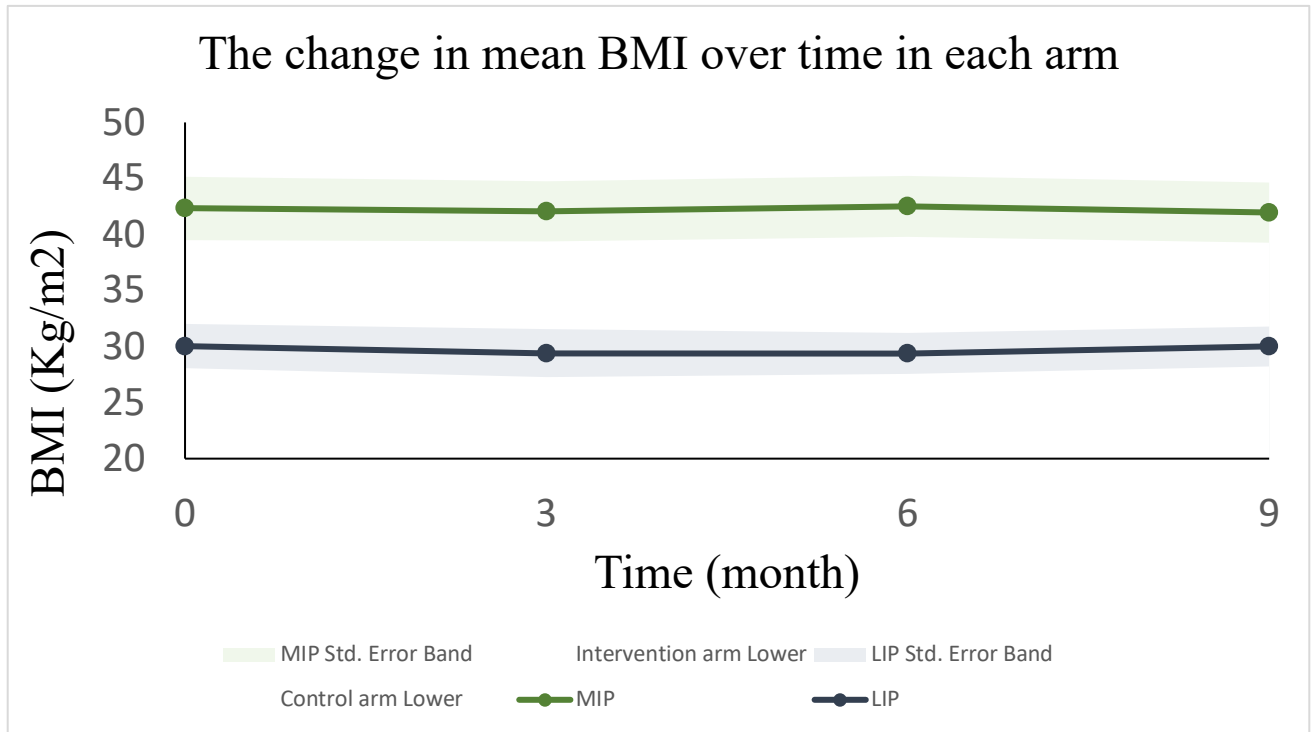
Appendix 5. A line graph displaying the overall trend in PHQ-9 scores over time in each arm

The change in mean PHQ-9 over time in each arm

LIP Standard Error Band　MIP Standard Error Band　MIP　LIP
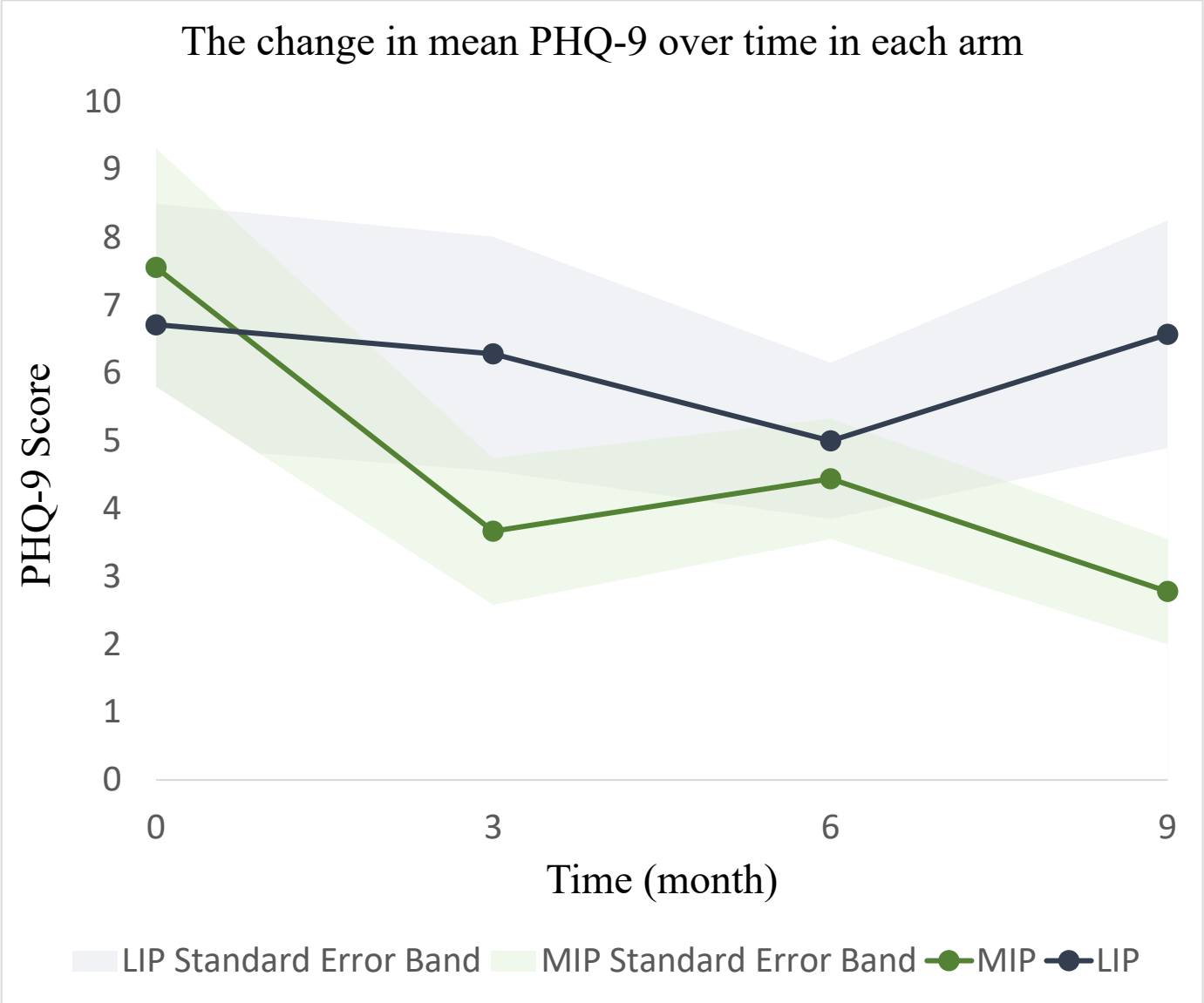
Appendix 6. A line graph displaying the overall SF-36 general health trend over time in each arm

The change in mean SF-36 general health score over time in each arm
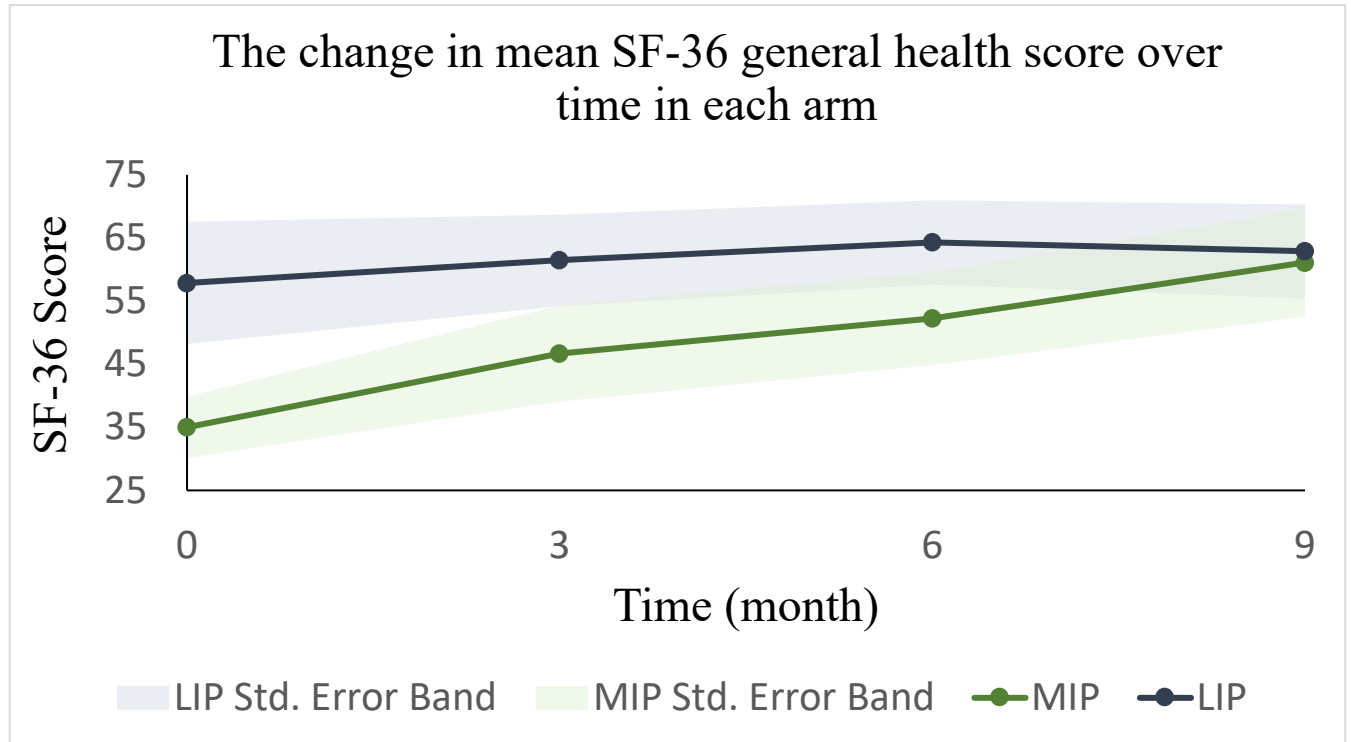
Appendix 7. A line graph displaying the overall trend in ISI scores over time in each arm

The change in mean ISI scores over time in each arm
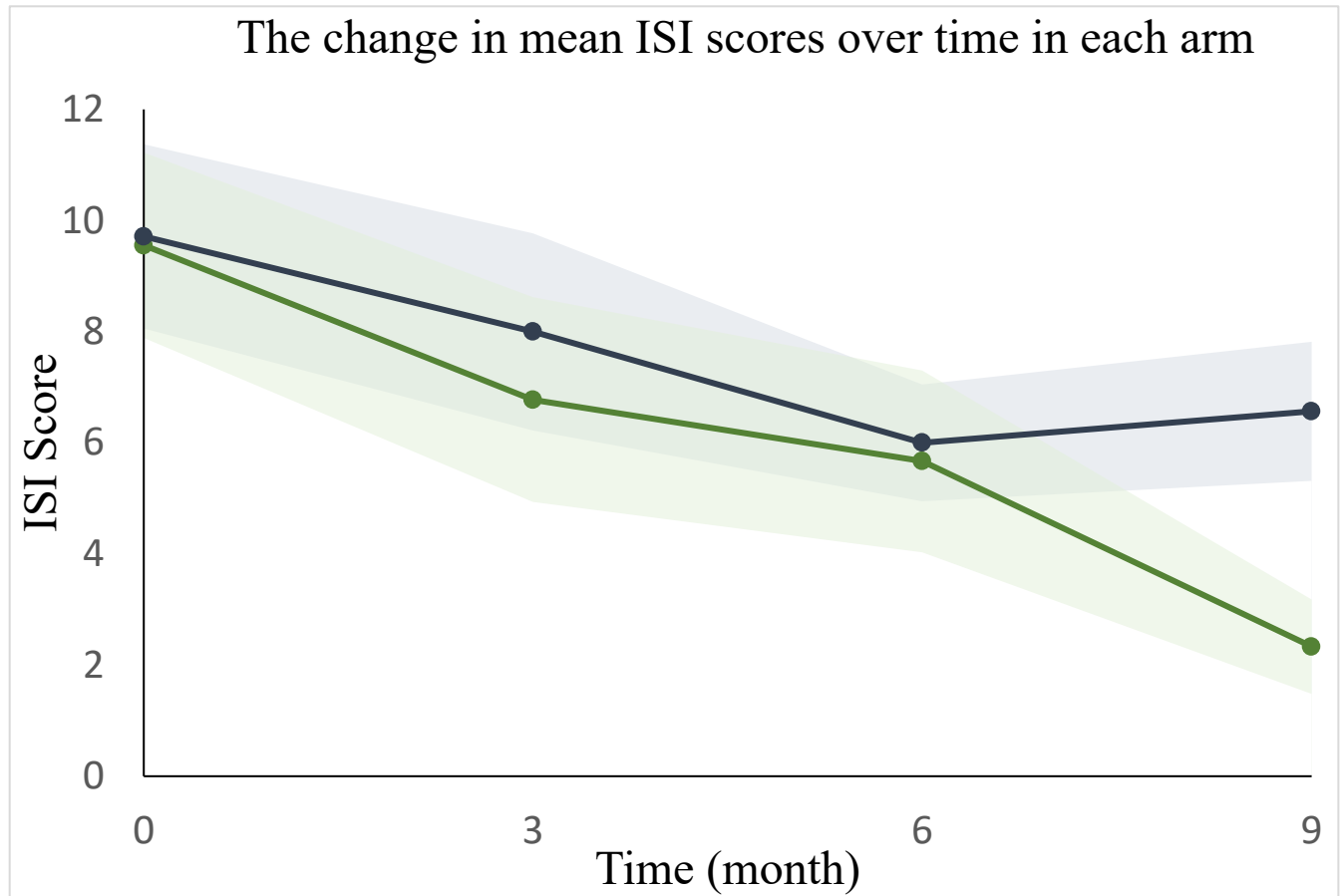
Appendix 8. A line graph displaying the overall trend in De Jong Gierveld scores over time in each arm

The change in mean De Jong Gierveld scores over time in each arm

Appendix 9. A line graph displaying the overall trend in PSS-10 scores over time in each arm

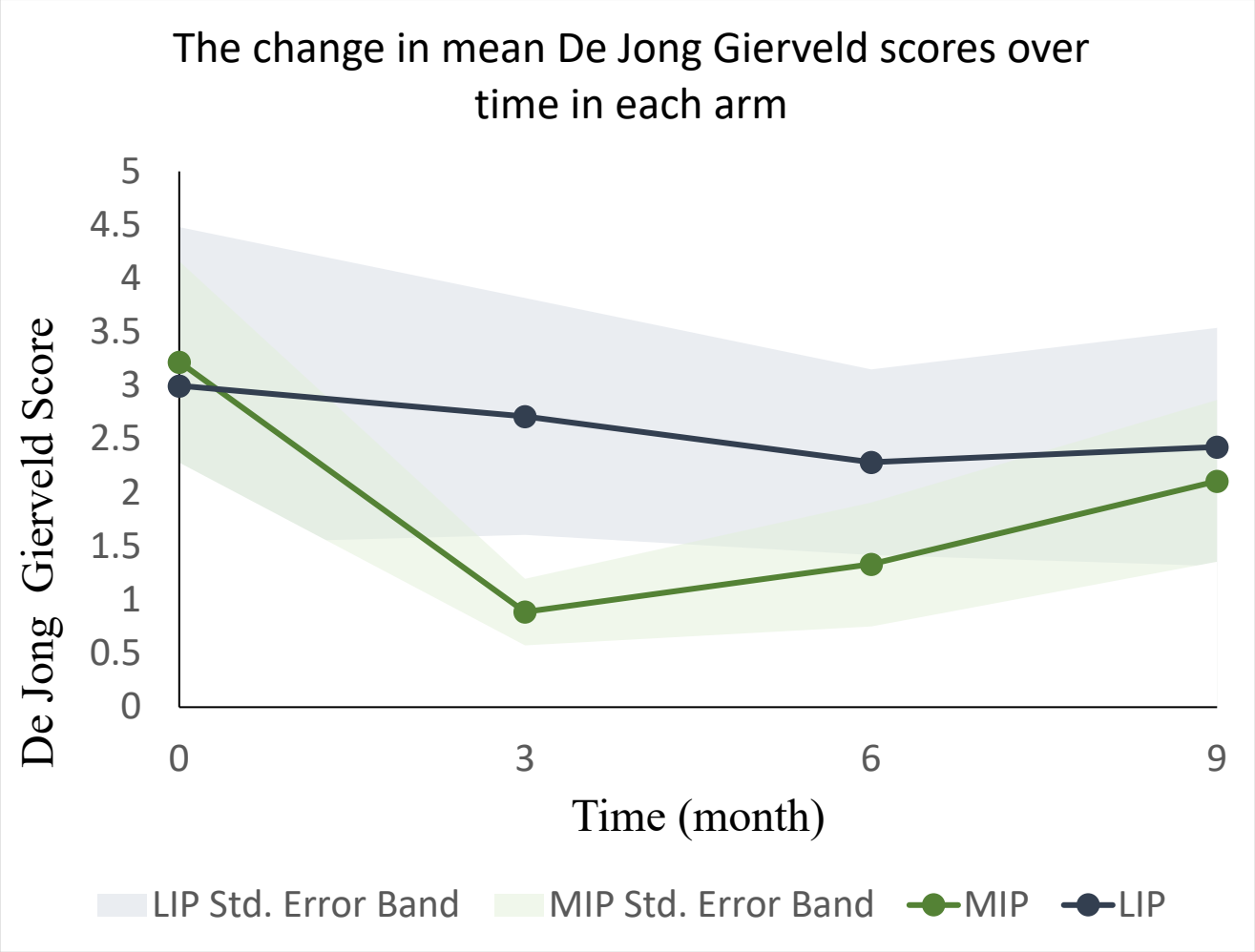The change in mean PSS-10 scores over time in each arm
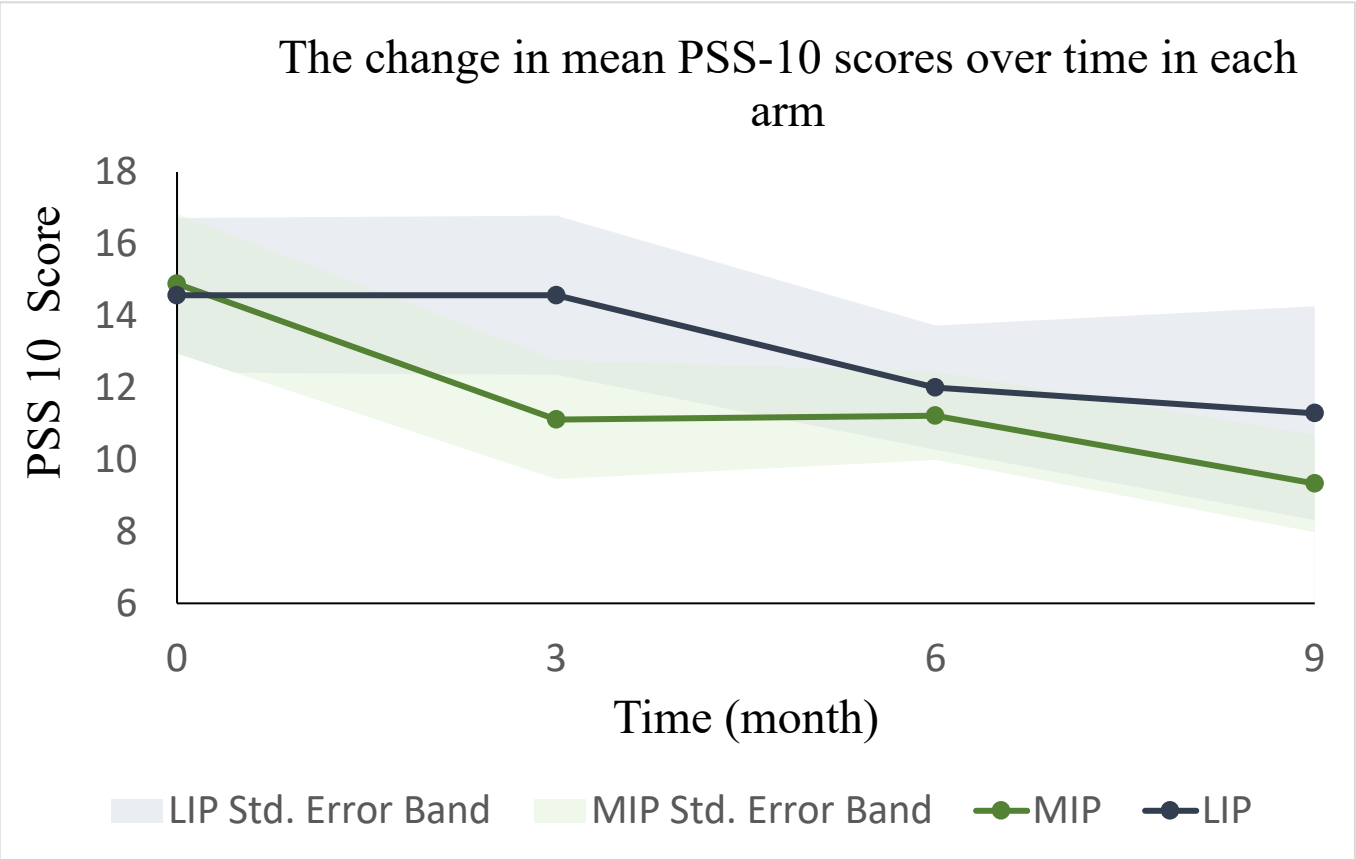
References

1. Roberts KC, Rao DP, Bennett TL, Loukine L, Jayaraman GC. Prevalence and patterns of chronic disease multimorbidity and associated determinants in Canada. *Chronic Dis Inj Can*. 2015;35(6):87-94. doi:10.24095/hpcdp.35.6.01

2. Public Health Agency of Canada. *Preventing Chronic Disease Strategic Plan 2013-2016.*; 2013.

3. Turner J. Emotional dimensions of chronic disease. *West J Med*. 2000;172(2):124-128. doi:10.1136/ewjm.172.2.124

4. Patten SB, Beck CA, Kassam A, Williams JVA, Barbui C, Metz LM. Long-term medical conditions and major depression: Strength of association for specific conditions in the general population. *Can J Psychiatry*. 2005;50(4):195-202. doi:10.1177/070674370505000402

5. Chapman DP, Perry GS, Strine TW. The vital link between chronic disease and depressive disorders. *Prev Chronic Dis*. 2005.

6. Clarke DM, Currie KC. Depression, anxiety and their relationship with chronic diseases: A review of the epidemiology, risk and treatment evidence. *Med J Aust*. 2009.

7. Smetanin P, Stiff D, Briante C, Adair CE, Ahmad S, Khan M. *Life at Risk Analysis of The Impact of Mental Illness in Canada*. Toronto; 2011. https://www.mentalhealthcommission.ca/sites/default/files/MHCC_Report_Base_Case_FINAL_ENG_0_0.pdf. Accessed January 20, 2018.

8. Kornblith a B, Herr HW, Ofman US, Scher HI, Holland JC. Quality of life of patients with prostate cancer and their spouses. The value of a data base in clinical care. *Cancer*. 1994. doi:10.1002/1097-0142(19940601)73:11<2791::AID-CNCR2820731123>3.0.CO;2-9

9. Weitzenkamp DA, Gerhart KA, Charlifue SW, Whiteneck GG, Savic G. Spouses of spinal cord injury survivors: The added impact of caregiving. *Arch Phys Med Rehabil*. 1997. doi:10.1016/S0003-9993(97)90194-5

10. Sharpe D, Rossiter L. Siblings of children with a chronic illness: a meta-analysis. *J Pediatr Psychol*. 2002.

11. Blakemore A, Dickens C, Guthrie E, et al. Depression and anxiety predict health-related quality of life in chronic obstructive pulmonary disease: Systematic review and meta-analysis. *Int J COPD*. 2014. doi:10.2147/COPD.S58136

12. Pinquart M, Shen Y. Depressive symptoms in children and adolescents with chronic physical illness: An updated meta-analysis. *J Pediatr Psychol*. 2011. doi:10.1093/jpepsy/jsq104

13. Patra, J., Popova, S., Rehm, J., Bondy, S., Flint, R., & Giesbrecht N. *Economic Cost of Chronic Disease in Canada.*; 2007.

14. Lim KL, Jacobs P, Ohinmaa A, Schopflocher D, Dewa CS. A new population-based measure of the economic burden of mental illness in Canada. *Chronic Dis Can*. 2008.

15. Propel Center for Population Health Imapct. Chronic Disease Prevention Primer. https://uwaterloo.ca/propel/sites/ca.propel/files/uploads/files/cdp_primer_v2.0_posted_20150420.pdf. Accessed January 20, 2018.

16. Velten J, Lavallee KL, Scholten S, et al. Lifestyle choices and mental health: A representative population survey. *BMC Psychol*. 2014;2(1). doi:10.1186/s40359-014-

0055-y

17. Walsh R. Lifestyle and mental health. *Am Psychol*. 2011;66(7):579-592. doi:10.1037/a0021769

18. Richardson CR, Faulkner G, McDevitt J, Skrinar GS, Hutchinson DS, Piette JD. Integrating Physical Activity Into Mental Health Services for Persons With Serious Mental Illness. *Psychiatr Serv*. 2005. doi:10.1176/appi.ps.56.3.324

19. Chacón F, Mora F, Gervás-Ríos A, Gilaberte I. Efficacy of lifestyle interventions in physical health management of patients with severe mental illness. *Ann Gen Psychiatry*. 2011. doi:10.1186/1744-859X-10-22

20. Hamovitch EK, Choy-Brown M, Stanhope V. Person-Centered Care and the Therapeutic Alliance. *Community Ment Health J*. 2018;54(7):951958.

21. Epstein RM, Fiscella K, Lesser CS, Stange KC. Why The Nation Need A Policy Push On Patient -Centered Health Care. *Health Aff*. 2010. doi:10.1377/hlthaff.2009.0888

22. Agras WS, Eldredge K, Marnell M. One-Year Follow-Up of Cognitive-Behavioral Therapy for Obese Individuals With Binge Eating Disorder. *J Consult Clin Psychol*. 1997;65(2):343-347. doi:10.1037/0022-006X.65.2.343

23. Cuijpers P, Berking M, Andersson G, Quigley L, Kleiboer A, Dobson KS. A meta-analysis of cognitive-behavioural therapy for adult depression, alone and in comparison with other treatments. *Can J Psychiatry*. 2013;58(7):376-385. doi:10.1177/070674371305800702

24. Otte C. Cognitive behavioral therapy in anxiety disorders: Current state of the evidence. *Dialogues Clin Neurosci*. 2011;13(4):413-421. doi:10.1186/1471-244X-14-S1-S1

25. Tsiros MD, Sinn N, Brennan L, et al. Cognitive behavioral therapy improves diet and body composition in overweight and obese adolescents. *Am J Clin Nutr*. 2008. doi:10.1093/ajcn/87.5.1134

26. Hauswirth K. Cognitive-behavioral therapy for addictions and substance abuse. In: *Salem Press Encyclopedia of Health*. ; 2014:2.

27. Glanz K, Bishop DB. The Role of Behavioral Science Theory in Development and Implementation of Public Health Interventions. *Annu Rev Public Health*. 2010;31(1):399-418. doi:10.1146/annurev.publhealth.012809.103604

28. Glanz K, Rimer BK, Viswanath K (Kasisomayajula). Health behavior : theory, research, and practice. In: *Health Behavior and Health Education*. ; 2015.

29. Painter JE, Borba CPC, Hynes M, Mays D, Glanz K. The Use of Theory in Health Behavior Research from 2000 to 2005: A Systematic Review. *Ann Behav Med*. 2008. doi:10.1007/s12160-008-9042-y

30. Strecher VJ, Seijts GH, Kok GJ, et al. Goal setting as a strategy for health behavior change. *Health Educ Q*. 1995;22(2):190-200. doi:10.1177/109019819502200207

31. Clark MM, Bradley KL, Jenkins SM, et al. Improvements in Health Behaviors, Eating Self-Efficacy, and Goal-Setting Skills Following Participation in Wellness Coaching. *Am J Heal Promot*. 2016;30(6):458-464. doi:10.4278/ajhp.140627-QUAL-304

32. Mann DM, Palmisano J, Lin JJ. A pilot randomized trial of technology-assisted goal setting to improve physical activity among primary care patients with prediabetes. *Prev Med Reports*. 2016. doi:10.1016/j.pmedr.2016.05.012

33. Bailey RR. Goal Setting and Action Planning for Health Behavior Change. *Am J Lifestyle Med*. 2017:155982761772963. doi:10.1177/1559827617729634

34. Gollwitzer PM, Sheeran P. Implementation Intentions and Goal Achievement: A Meta-

analysis of Effects and Processes. *Adv Exp Soc Psychol*. 2006;38:69-119.
doi:10.1016/S0065-2601(06)38002-1

35. Sheeran P. Intention—Behavior Relations: A Conceptual and Empirical Review. *Eur Rev Soc Psychol*. 2002. doi:10.1080/14792772143000003

36. Kersten P, McCambridge A, M. Kayes N, Theadom A, McPherson KM. Bridging the gap between goal intentions and actions: A systematic review in patient populations. *Disabil Rehabil*. 2015. doi:10.3109/09638288.2014.935874

37. Watkins E. Dysregulation in level of goal and action identification across psychological disorders. *Clin Psychol Rev*. 2011;31(2):260-278. doi:10.1016/j.cpr.2010.05.004

38. Dickson JM, Moberly NJ. Reduced Specificity of Personal Goals and Explanations for Goal Attainment in Major Depression. *PLoS One*. 2013;8(5). doi:10.1371/journal.pone.0064512

39. McKinnon CR, Garvin JT. Weight Reduction Goal Achievement Among Veterans With Mental Health Diagnoses. *J Am Psychiatr Nurses Assoc*. 2018;1078390318. doi:10.1177/1078390318800594

40. Frijda NH. The emotions. *Emot*. 1986. doi:10.1093/0199253048.001.0001

41. Frijda NH. The Laws of Emotion. *Am Psychol*. 1988. doi:10.1037/0003-066X.43.5.349

42. Klug HJP, Maier GW. Linking Goal Progress and Subjective Well-Being: A Meta-analysis. *J Happiness Stud*. 2014. doi:10.1007/s10902-013-9493-0

43. Deci EL, Ryan RM. Self-determination theory: A macrotheory of human motivation, development, and health. In: *Canadian Psychology*. ; 2008. doi:10.1037/a0012801

44. Schmuck P, Kasser T, Ryan RM. Intrinsic and extrinsic goals: Their structure and relationship to well-being in German and U.S. college students. *Soc Indic Res*. 2000. doi:10.1023/A:1007084005278

45. Erikson EH. Childhood and society. (2nd Ed.). *Child Soc (2nd Ed)*. 1964. doi:10.1080/09602010343000538

46. White M, Mayer M, Vanderlind WM, Allswede D. Evaluation of a Behavioral Self-Care Intervention for Public Health Students. *Am J Heal Educ*. 2017;49(1):40-47.

47. Canadian Mental Health Association Ontario. *Every Door Is the Right Door: Towards a 10-Year Mental Health and Addictions Strategy*.; 2009.

48. Children's Mental Health Ontario. *Backlog at Community-Based Child and Youth Mental Health Centres Sends Kids to Hospitals at Alarming Rates*. Ontario; 2017.

49. Addictions and Mental Health Ontario. *Where Change Happens: Addictions and Mental Health Ontario 2018 Priorities*. Toronto; 2018.

50. Mental Health Commission of Canada. *Changing Directions, Changing Lives: The Mental Health Strategy for Canada*. Calgary; 2012.

51. Patsopoulos NA. A pragmatic view on pragmatic trials. *Dialogues Clin Neurosci*. 2011. doi:10.1016/j.jclinepi.2009.01.012

52. Cohen SL, Rice CA. Maximizing the therapeutic effectiveness of small psychotherapy groups. *Group*. 1985. doi:10.1007/BF01458260

53. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. *J Gen Intern Med*. 2001;16(9):606-613. doi:10.1046/j.1525-1497.2001.016009606.x

54. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: The GAD-7. *Arch Intern Med*. 2006;166(10):1092-1097. doi:10.1001/archinte.166.10.1092

55. Bastien CH, Vallières A, Morin CM. Validation of the insomnia severity index as an

outcome measure for insomnia research. *Sleep Med*. 2001;2(4):297-307. doi:10.1016/S1389-9457(00)00065-4

56.   Gierveld JDJ, Tilburg T Van. A 6-Item Scale for Overall, Emotional, and Social Loneliness: Confirmatory Tests on Survey Data. *Res Aging*. 2006;28(5):582-598. doi:10.1177/0164027506289723

57.   Grygiel P, Humenny G, Rebisz S. Using the De Jong Gierveld Loneliness Scale With Early Adolescents: Factor Structure, Reliability, Stability, and External Validity. *Assessment*. December 2016. doi:10.1177/1073191116682298

58.   de Jong Gierveld J, van Tilburg T. The De Jong Gierveld short scales for emotional and social loneliness: Tested on data from 7 countries in the UN generations and gender surveys. *Eur J Ageing*. 2010. doi:10.1007/s10433-010-0144-6

59.   Gierveld JDJ, Van Tilburg T. A 6-item scale for overall, emotional, and social loneliness: Confirmatory tests on survey data. *Res Aging*. 2006;28(5):582-598. doi:10.1177/0164027506289723

60.   Wang M. Generalized Estimating Equations in Longitudinal Data Analysis: A Review and Recent Developments. *Adv Stat*. 2014. doi:10.1155/2014/303728

61.   Homish GG, Edwards EP, Eiden RD, Leonard KE. Analyzing family data: A GEE approach for substance use researchers. *Addict Behav*. 2010. doi:10.1016/j.addbeh.2010.01.002

62.   Burton P, Gurrin L, Sly P. Clustered Data: Extending the Simple Linear Regression Model to Account for Correlated Responses: An Introduction to Generalized Estimating Equations and Multi-Level Mixed Modelling. In: *Tutorials in Biostatistics*. ; 2005. doi:10.1002/0470023724.ch1a

63.   Liang KY, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika*. 1986. doi:10.1093/biomet/73.1.13

64.   Cui J. QIC program and model selection in GEE analyses. *Stata J*. 2007. doi:10.3760/cma.j.issn.1003-9406.2011.02.007

65.   Pan W. Akaike's information criterion in generalized estimating equations. *Biometrics*. 2001. doi:10.1111/j.0006-341X.2001.00120.x

66.   IBM Corp. IBM SPSS Statistics for Mac, Version 25.0. *IBM*. 2017.

67.   Uher R, Perlis RH, Placentino A, et al. Self-report and clinician-rated measures of depression severity: Can one replace the other? *Depress Anxiety*. 2012. doi:10.1002/da.21993

68.   Duffy FF, Katzelnick DJ, Regier DA, Chung H, Rae DS, Trivedi MH. Depression Outcomes in Psychiatric Clinical Practice: Using a Self-Rated Measure of Depression Severity. *Psychiatr Serv*. 2011. doi:10.1176/appi.ps.62.8.929

69.   Hróbjartsson A, Emanuelsson F, Thomsen ASS, Hilden J, Brorson S. Bias due to lack of patient blinding in clinical trials. A systematic review of trials randomizing patients to blind and nonblind sub-studies. *Int J Epidemiol*. 2014. doi:10.1093/ije/dyu115

70.   Nunan D, Aronson J, Bankhead C. Catalogue of bias: attrition bias. *BMJ evidence-based Med*. 2018. doi:10.1136/ebmed-2017-110883

71.   Freund AM, Hennecke M. Changing eating behaviour vs. losing weight: The role of goal focus for weight loss in overweight women. *Psychol Heal*. 2012. doi:10.1080/08870446.2011.570867

72.   Isaac F, Greenwood KM. The relationship between insomnia and depressive symptoms: Genuine or artifact? *Neuropsychiatr Dis Treat*. 2011. doi:10.2147/NDT.S16267

73. Mushtaq R, Shoib S, Shah T, Mushtaq S. Relationship between loneliness, Psychiatric disorders and physical health ? A review on the psychological aspects of loneliness. *J Clin Diagnostic Res*. 2014. doi:10.7860/JCDR/2014/10077.4828

74. Institute of Medicine (US) Committee on Health and Behavior: Research P and PW (DC): NAP (US). TNACR funded by NI of H, Institute of Medicine (US) Committee on Health and Behavior: Research P and PW (DC): NAP (US). TNACR funded by NI of H. *Health and Behavior: The Interplay of Biological, Behavioral, and Societal Influences. 5. Individuals and Families: Models and Interventions*.; 2001.

75. Spahn JM, Reeves RS, Keim KS, et al. State of the Evidence Regarding Behavior Change Theories and Strategies in Nutrition Counseling to Facilitate Health and Food Behavior Change. *J Am Diet Assoc*. 2010. doi:10.1016/j.jada.2010.03.021

76. Afifi M. Gender differences in mental health. *Singapore Med J*. 2007.